

*2006 Bills
of Interest*

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 2198

VERSION: AMENDED APRIL 18, 2006

AUTHOR: HOUSTON

SPONSOR: MEDICAL BOARD OF CALIFORNIA

RECOMMENDED POSITION: NONE

SUBJECT: HEALTH CARE: CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

Existing Law:

Existing law establishes the California Intractable Pain Treatment Act and the Pain Patient's Bill of Rights. (B&P 2241.5 and H&S 124960)

This Bill:

- 1) Defines "addict" as a person whose actions are characterized by one or more of the following: 1) impaired control over drug use; 2) compulsive use; 3) continued use despite harm. (B&P 2241 and H&S 11156 Amended)
- 2) Requires an "appropriate prior examination" instead of a good faith prior examination of a patient be conducted prior to prescribing, dispensing, or furnishing dangerous drugs or devices. (B&P 2242.1 Amended)

Comment:

1) Author's Intent. The author's intent is to update the law with regard to pain management.

2) Background. In August 2005, the Medical Board of California (MBC) convened a taskforce to review California law regarding pain management. The review was conducted, in part, to respond to findings in two University of Wisconsin's Pain and Policy Studies Group (group) studies, "Achieving Balance in Federal and State Policy: a Guide to Evaluation" updated in 2004, and "Achieving Balance in State Pain Policy, A Progress Report Card" also updated in 2004. (Excerpts of the studies are attached.) The group gave California a grade of "C" on the group's report card.

The taskforce met several times to discuss and draft proposed legislation to amend California's pain management laws. Board staff, as well as Josh Room (Deputy Attorney General), attended a taskforce meeting in January 2006, to provide comments on the legislative proposal. The initial proposal included draft language to amend B&P 4301(e), Unprofessional Conduct. The amendment would have defined the phrase "clearly excessive" in the context of unprofessional conduct in furnishing excessive quantities of controlled substances. After some discussion, the taskforce dropped the proposal to amend B&P 4301(e).

The language in AB 2198 is the product of the taskforce meetings and, while the bill does not amend pharmacy law, there is concern that the definition of "clearly excessive" may leak over into B&P 4301.

3) April 18 Amendments. The amendments on April 18th among other things, removed the definition of "clearly excessive" in B&P 725. This definition was of concern to the board because of the definition's potential to be applied to B&P 4301 during disciplinary proceedings. This application might have required the board to disprove a "medical or pharmacological basis" for excessive furnishing; this would be a new and substantial burden requiring additional expert testimony and proof from the board.

3) Previous Legislation. SB 402 (Chapter 839, Statutes of 1997) established the Pain Patient's Bill of Rights and stated the legislative findings and declarations regarding the value of opiate drugs to persons suffering from severe chronic intractable pain. It, among other things, authorized a physician who refuses to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain to inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates, and authorized a physician who prescribes opiates to prescribe a dosage deemed medically necessary.

SB 1802 (Chapter 1588, Statutes of 1990) established the California Intractable Pain Treatment Act that authorized a licensed physician to treat intractable pain with narcotic drugs without being subject to Medical Board discipline - subject to specified safeguards to assure that the treatment was medically and therapeutically appropriate.

4) History.

2006

Apr. 19	Re-referred to Com. on HEALTH.
Apr. 18	Read second time and amended.
Apr. 17	From committee: Amend, do pass as amended, and re-refer to Com. On HEALTH. (Ayes 9. Noes 0.) (April 17).
Mar. 30	Re-referred to Com. on B. & P., and then to Com. on HEALTH.
Mar. 29	Re-referred to Com. on HEALTH.
Mar. 28	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 20	Referred to Coms. on HEALTH and B. & P.
Mar. 30	Re-referred to Com. on B. & P., and then to Com. on HEALTH.
Mar. 29	Re-referred to Com. on HEALTH.
Mar. 28	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 20	Referred to Coms. on HEALTH and B. & P.
Feb. 23	
Feb. 22	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 18, 2006
AMENDED IN ASSEMBLY MARCH 28, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2198

Introduced by Assembly Member Houston

February 22, 2006

An act to amend Sections 725, 2241, 2242, and 2242.1 of, and to repeal and add Section 2241.5 of, the Business and Professions Code, and to amend Section 11156 of the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2198, as amended, Houston. Health care: controlled substances and dangerous drugs.

Existing law makes it unprofessional conduct for specified health care providers to engage in repeated acts of clearly excessive prescribing or administering of drugs or treatment, ~~unless the health care provider is subject to specified penalties. Existing law prohibits disciplinary action under these provisions against a physician and surgeon who is acting lawfully~~ in compliance with the California Intractable Pain Treatment Act.

This bill would ~~delete the provision prohibiting, in addition, prohibit disciplinary action under these provisions against a physician and surgeon who is in compliance with the California Intractable Pain Treatment Act. The bill would define "clearly excessive" to mean an amount or extent that is without substantial medical basis and is substantially greater than the usual amount of prescribing, administering, or use of the therapeutic modalities has a medical basis~~

for prescribing, furnishing, dispensing, or administering of a dangerous drug or prescription controlled substance.

Existing law, the Medical Practice Act, provides for the licensing and regulation of physicians and surgeons by the Medical Board of California, and the violation of specified provisions of the act is a crime. The California Intractable Pain Treatment Act, in the Medical Practice Act, authorizes a physician and surgeon to prescribe or administer controlled substances to a person in the course of treatment for a diagnosed condition causing intractable pain, except in certain circumstances, and prohibits disciplinary action against a physician and surgeon for such action.

~~This bill would define addict for purposes of these provisions. The bill would delete these provisions and would instead authorize a physician and surgeon to prescribe for, or dispense or administer to, a person *under his or her treatment* for a medical condition drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including intractable pain. The bill would require the physician and surgeon to exercise reasonable care in determining whether a particular patient or condition, or complexity of the patient's treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with, or referral to, a more qualified specialist. A violation of this requirement would be a crime. *Although the bill would exempt a physician and surgeon acting in accordance with these provisions from disciplinary action for the prescribing, dispensing, or administering of dangerous drugs or prescription controlled substances, it would expressly provide that the power of the board to deny, revoke, or suspend a license not be affected with regard to specified actions and that the governing body of a hospital not be prohibited from taking certain disciplinary action against a physician and surgeon.*~~

Existing law, except as specified, prohibits a person from prescribing or administering or dispensing a controlled substance to an addict or habitual user *or a person representing himself or herself as an addict or habitual user*. Existing law generally makes it unprofessional conduct for a physician and surgeon to prescribe, sell, furnish, give away, or administer certain drugs to an addict or habitué, or to offer to do so, ~~but contains certain exceptions from this provision~~ *except as specified.*

This bill would delete the provision making it unprofessional conduct for a physician and surgeon to prescribe, sell, furnish, give

away, or administer certain drugs to an addict or habitué, or to offer to do so. The bill would authorize a physician and surgeon to prescribe, dispense, or administer prescription drugs, including prescription controlled substances, (1) to an addict under his or her treatment for a condition other than maintenance on, or detoxification from, prescription drugs or controlled substances and (2) under specified conditions to an addict for purposes of maintenance on, or detoxification from, prescription drugs or controlled substances. The bill would also authorize prescription drugs or controlled substances to be administered or applied by a physician and surgeon, or by a registered nurse acting under his or her instruction and supervision, in certain circumstances. A violation of ~~this requirement~~ *these requirements* would be a crime. *The bill would also revise the prohibition against prescribing, administering, or dispensing a controlled substance to an addict or habitual user to delete the reference to a habitual user, and to exempt activity pursuant to the above authorization. The bill would define addict for purposes of these provisions.*

Existing law makes it unprofessional conduct for a physician and surgeon to prescribe, dispense, or furnish dangerous drugs without a good faith prior examination and medical indication. Existing law also, with specified exceptions, prohibits a person or entity from prescribing, dispensing, or furnishing, or causing to be prescribed, dispensed, or furnished, dangerous drugs or dangerous devices on the Internet for delivery to a person in California without a good faith prior examination and medical indication.

This bill would, for purposes of these provisions, require an appropriate prior examination instead of a good faith prior examination. The bill would make related legislative findings.

Because this bill would create new crimes, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature hereby finds and declares the
2 following:

3 (a) The investigation and prosecution of pain management
4 cases in California have evolved over the past 15 years.

5 (b) The Pain Patient's Bill of Rights and the Intractable Pain
6 Treatment Act were created to ensure patients received adequate
7 pain medication and to protect a physician and surgeon from
8 being disciplined solely because of the amounts of controlled
9 substances he or she prescribed or administered.

10 (c) California recognizes that prescription medication,
11 including controlled substances, can play a critical role in the
12 treatment of pain, and, in and of itself, is an insufficient basis to
13 determine if a physician and surgeon has violated the standard of
14 care in his or her treatment of pain management patients.

15 ~~(d) California also recognizes that the Intractable Pain~~
16 ~~Treatment Act may be an impediment to easily accessible pain~~
17 ~~treatment which can be confusing to both licensees and~~
18 ~~regulating entities. It can also provide a false sense of security to~~
19 ~~licensees who may erroneously believe it immunizes them from~~
20 ~~any actions against their license.~~

21 *(d) Under-treatment of pain, including the use of opioids, is a*
22 *continuing problem in the State of California, and some terms of*
23 *the Intractable Pain Treatment Act are outdated and confusing.*

24 (e) In recognition of the Medical Board of California's
25 consumer protection mandates, and in an attempt to provide
26 better treatment of pain patients, as well as protect the public
27 through the appropriate investigation and prosecution of those
28 who violate the standard of care when treating pain patients, the
29 Legislature recognizes that it is time to reflect upon the current
30 state of pain management to aid both those who treat pain
31 patients, as well as those who investigate and prosecute
32 physicians and surgeons.

33 SEC. 2. Section 725 of the Business and Professions Code is
34 amended to read:

35 725. (a) Repeated acts of clearly excessive prescribing,
36 furnishing, dispensing, or administering of drugs or treatment,
37 repeated acts of clearly excessive use of diagnostic procedures,
38 or repeated acts of clearly excessive use of diagnostic or

1 treatment facilities as determined by the standard of the
2 community of licensees is unprofessional conduct for a physician
3 and surgeon, dentist, podiatrist, psychologist, physical therapist,
4 chiropractor, or optometrist.

5 (b) Any person who engages in repeated acts of clearly
6 excessive prescribing or administering of drugs or treatment is
7 guilty of a misdemeanor and shall be punished by a fine of not
8 less than one hundred dollars (\$100) nor more than six hundred
9 dollars (\$600), or by imprisonment for a term of not less than 60
10 days nor more than 180 days, or by both the fine and
11 imprisonment.

12 (c) ~~For purposes of this section, "clearly excessive" shall mean~~
13 ~~an amount or extent that is both (1) without substantial medical~~
14 ~~basis and (2) substantially greater than the usual amount of~~
15 ~~prescribing, administration, or use of therapeutic modalities.~~

16 (c) *A practitioner who has a medical basis for prescribing,*
17 *furnishing, dispensing, or administering dangerous drugs or*
18 *prescription controlled substances shall not be subject to*
19 *disciplinary action or prosecution under this section.*

20 (d) *No physician and surgeon shall be subject to disciplinary*
21 *action pursuant to this section for treating intractable pain in*
22 *compliance with Section 2241.5.*

23 SEC. 3. Section 2241 of the Business and Professions Code is
24 amended to read:

25 2241. (a) A physician and surgeon may prescribe, dispense,
26 or administer prescription drugs, including prescription
27 controlled substances, to an addict under his or her treatment for
28 a condition other than maintenance on, or detoxification from,
29 prescription drugs or controlled substances.

30 (b) A physician and surgeon may only prescribe, dispense, or
31 administer prescription drugs or prescription controlled
32 substances to an addict for purposes of maintenance on or
33 detoxification from prescription drugs or controlled substances as
34 set forth in subdivision (c) or in Sections 11215, 11217, 11217.5,
35 11218, 11219, and 11220 of the Health and Safety Code. Nothing
36 in this subdivision shall authorize a physician and surgeon to
37 prescribe, dispense, or administer dangerous drugs or controlled
38 substances to a person he or she knows or reasonably believes is
39 using or will use the drugs or substances for a nonmedical
40 purpose.

1 (c) Notwithstanding subdivision (a), prescription drugs or
2 controlled substances may also be administered or applied by a
3 physician and surgeon, or by a registered nurse acting under his
4 or her instruction and supervision, under the following
5 circumstances:

6 (1) Emergency treatment of a patient whose addiction is
7 complicated by the presence of incurable disease, acute accident,
8 illness, or injury, or the infirmities attendant upon age.

9 (2) Treatment of addicts in state-licensed institutions where
10 the patient is kept under restraint and control, or in city or county
11 jails or state prisons.

12 (3) Treatment of addicts as provided for by Section 11217.5 of
13 the Health and Safety Code.

14 (d) For purposes of this section and Section 2241.5, "addict"
15 means a person whose actions are characterized by one or more
16 of the following:

17 (1) Impaired control over drug use.

18 (2) Compulsive use.

19 (3) Continued use despite ~~harm and craving~~: *harm*.

20 (4) *Craving*.

21 SEC. 4. Section 2241.5 of the Business and Professions Code
22 is repealed.

23 SEC. 5. Section 2241.5 is added to the Business and
24 Professions Code, to read:

25 2241.5. (a) A physician and surgeon may prescribe for, or
26 dispense or administer to, a person under his or her treatment for
27 a medical condition dangerous drugs or prescription controlled
28 substances for the treatment of pain or a condition causing pain,
29 including, but not limited to, intractable pain.

30 ~~(b) A physician and surgeon's authority under this section~~
31 ~~shall be subject to the provisions of Sections 725, 2234, 2241,~~
32 ~~2242, and 2242.1, and Sections 11152, 11153, and 11154 of the~~
33 ~~Health and Safety Code. Nothing in this section shall authorize a~~
34 ~~physician and surgeon to prescribe, administer or dispense~~
35 ~~dangerous drugs or controlled substances to a person he or she~~
36 ~~knows or reasonably believes is using or will use the drugs or~~
37 ~~substances for a nonmedical purpose.~~

38 (c) Any physician and surgeon has the legal authority to treat a
39 patient for pain using dangerous drugs or prescription controlled
40 substances but the prescribing, administering, or dispensing

1 ~~physician and surgeon shall exercise reasonable care in~~
2 ~~determining whether a particular patient or condition, or~~
3 ~~complexity of the patient's treatment, including, but not limited~~
4 ~~to, a current or recent pattern of drug abuse, requires consultation~~
5 ~~with or referral to a more qualified specialist.~~

6 *(b) No physician and surgeon shall be subject to disciplinary*
7 *action for prescribing, dispensing, or administering dangerous*
8 *drugs or prescription controlled substances in accordance with*
9 *this section.*

10 *(c) This section shall not affect the power of the board to deny,*
11 *revoke, or suspend the license of a physician and surgeon who*
12 *does any of the following:*

13 *(1) Violates Section 2234, 2241, 2242, or 2242.1.*

14 *(2) Fails to keep complete and accurate records of purchases*
15 *and disposals of substances listed in the California Uniform*
16 *Controlled Substances Act (Division 10 (commencing with*
17 *Section 11000) of the Health and Safety Code) or controlled*
18 *substances scheduled in the federal Comprehensive Drug Abuse*
19 *Prevention and Control Act of 1970 (21 U.S.C. Sec. 801 et seq.),*
20 *or pursuant to the federal Comprehensive Drug Abuse*
21 *Prevention and Control Act of 1970. A physician and surgeon*
22 *shall keep records of his or her purchases and disposals of these*
23 *controlled substances or dangerous drugs, including the date of*
24 *purchase, the date and records of the sale or disposal of the*
25 *drugs by the physician and surgeon, the name and address of the*
26 *person receiving the drugs, and the reason for the disposal or the*
27 *dispensing of the drugs to the person, and shall otherwise comply*
28 *with all state record keeping requirements for controlled*
29 *substances.*

30 *(3) Writes false or fictitious prescriptions for controlled*
31 *substances listed in the California Controlled Substances Act or*
32 *scheduled in the federal Comprehensive Drug Abuse Prevention*
33 *and Control Act of 1970.*

34 *(4) Prescribes, administers, or dispenses in violation of this*
35 *chapter, or in violation of Chapter 4 (commencing with Section*
36 *11150) or Chapter 5 (commencing with Section 11210) of*
37 *Division 10 of the Health and Safety Code.*

38 *(d) A physician and surgeon shall exercise reasonable care in*
39 *determining whether a particular patient or condition, or the*
40 *complexity of a patient's treatment, including, but not limited to,*

1 *a current or recent pattern of drug abuse, requires consultation*
2 *with, or referral to, a more qualified specialist.*

3 *(e) Nothing in this section shall prohibit the governing body of*
4 *a hospital from taking disciplinary actions against a physician*
5 *and surgeon pursuant to Sections 809.05, 809.4, and 809.5.*

6 SEC. 6. Section 2242 of the Business and Professions Code is
7 amended to read:

8 2242. (a) Prescribing, dispensing, or furnishing dangerous
9 drugs as defined in Section 4022 without an appropriate prior
10 examination and a medical indication, constitutes unprofessional
11 conduct.

12 (b) No licensee shall be found to have committed
13 unprofessional conduct within the meaning of this section if, at
14 the time the drugs were prescribed, dispensed, or furnished, any
15 of the following applies:

16 (1) The licensee was a designated physician and surgeon or
17 podiatrist serving in the absence of the patient's physician and
18 surgeon or podiatrist, as the case may be, and if the drugs were
19 prescribed, dispensed, or furnished only as necessary to maintain
20 the patient until the return of his or her practitioner, but in any
21 case no longer than 72 hours.

22 (2) The licensee transmitted the order for the drugs to a
23 registered nurse or to a licensed vocational nurse in an inpatient
24 facility, and if both of the following conditions exist:

25 (A) The practitioner had consulted with the registered nurse or
26 licensed vocational nurse who had reviewed the patient's records.

27 (B) The practitioner was designated as the practitioner to serve
28 in the absence of the patient's physician and surgeon or
29 podiatrist, as the case may be.

30 (3) The licensee was a designated practitioner serving in the
31 absence of the patient's physician and surgeon or podiatrist, as
32 the case may be, and was in possession of or had utilized the
33 patient's records and ordered the renewal of a medically
34 indicated prescription for an amount not exceeding the original
35 prescription in strength or amount or for more than one refilling.

36 (4) The licensee was acting in accordance with Section
37 120582 of the Health and Safety Code.

38 SEC. 7. Section 2242.1 of the Business and Professions Code
39 is amended to read:

1 2242.1. (a) No person or entity may prescribe, dispense, or
2 furnish, or cause to be prescribed, dispensed, or furnished,
3 dangerous drugs or dangerous devices, as defined in Section
4 4022, on the Internet for delivery to any person in this state,
5 without an appropriate prior examination and medical indication,
6 except as authorized by Section 2242.

7 (b) Notwithstanding any other provision of law, a violation of
8 this section may subject the person or entity that has committed
9 the violation to either a fine of up to twenty-five thousand dollars
10 (\$25,000) per occurrence pursuant to a citation issued by the
11 board or a civil penalty of twenty-five thousand dollars (\$25,000)
12 per occurrence.

13 (c) The Attorney General may bring an action to enforce this
14 section and to collect the fines or civil penalties authorized by
15 subdivision (b).

16 (d) For notifications made on and after January 1, 2002, the
17 Franchise Tax Board, upon notification by the Attorney General
18 or the board of a final judgment in an action brought under this
19 section, shall subtract the amount of the fine or awarded civil
20 penalties from any tax refunds or lottery winnings due to the
21 person who is a defendant in the action using the offset authority
22 under Section 12419.5 of the Government Code, as delegated by
23 the Controller, and the processes as established by the Franchise
24 Tax Board for this purpose. That amount shall be forwarded to
25 the board for deposit in the Contingent Fund of the Medical
26 Board of California.

27 (e) If the person or entity that is the subject of an action
28 brought pursuant to this section is not a resident of this state, a
29 violation of this section shall, if applicable, be reported to the
30 person's or entity's appropriate professional licensing authority.

31 (f) Nothing in this section shall prohibit the board from
32 commencing a disciplinary action against a physician and
33 surgeon pursuant to Section 2242.

34 SEC. 8. Section 11156 of the Health and Safety Code is
35 amended to read:

36 11156. (a) ~~No~~ Except as provided in Section 2241 of the
37 Business and Professions Code, no person shall prescribe for or
38 administer, or dispense a controlled substance to an addict, or to
39 any person representing himself or herself as such, except as
40 permitted by this division.

1 (b) For purposes of this section, “addict” means a person
2 whose actions are characterized by one or more of the following:

3 (1) Impaired control over drug use.

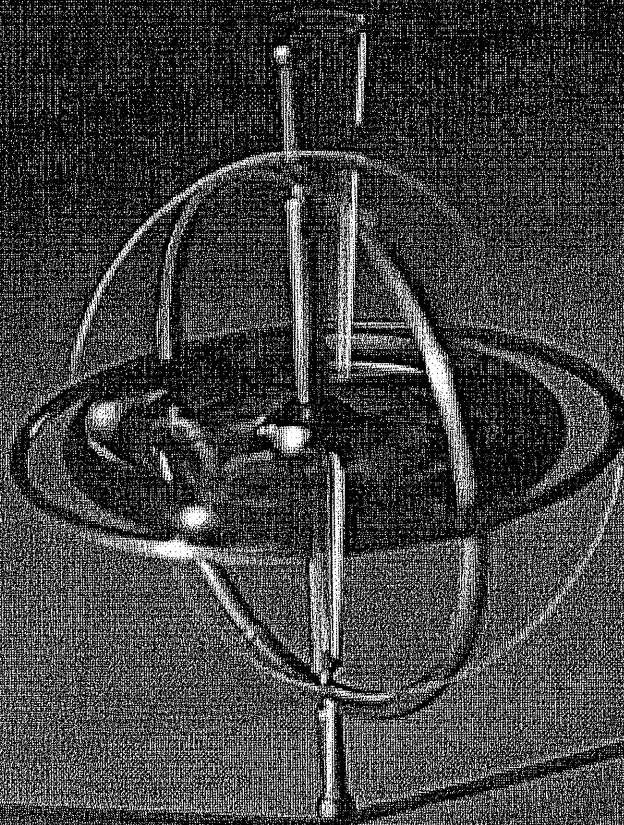
4 (2) Compulsive use.

5 (3) Continued use despite ~~harm and craving~~; *harm*.

6 (4) *Craving*.

7 SEC. 9. No reimbursement is required by this act pursuant to
8 Section 6 of Article XIII B of the California Constitution because
9 the only costs that may be incurred by a local agency or school
10 district will be incurred because this act creates a new crime or
11 infraction, eliminates a crime or infraction, or changes the
12 penalty for a crime or infraction, within the meaning of Section
13 17556 of the Government Code, or changes the definition of a
14 crime within the meaning of Section 6 of Article XIII B of the
15 California Constitution.

ACHIEVING BALANCE **in Federal & State Pain Policy:** **A Guide to Evaluation,** Second Edition



Pain & Policy Studies Group

University of Wisconsin

Comprehensive Cancer Center

www.medsch.wisc.edu/painpolicy

Updated February 2004

Supported by:

The Robert Wood Johnson Foundation

Executive Summary

Despite important progress, there continues to be a gap between the possibility and the reality of adequate pain management. Inadequate relief from pain is a serious public health problem in the United States for many underserved populations, including children, the elderly, minorities, nursing home patients, and people with limited financial resources. The pain problem has drawn the attention of a variety of professions, including medicine, pharmacy, nursing, social work, law, and bioethics. Public, professional, and private organizations are developing patient information and professional education; healthcare providers are offering pain management, palliative care, and end-of-life care services.

There are many safe and effective ways to treat pain. However, there is a medical consensus that opioid analgesics are indispensable for a variety of pain types, particularly if pain is severe. Opioid analgesics also have a potential for abuse, so their distribution is strictly regulated under federal and state controlled substances statutes and regulations.

A number of barriers interfere with pain management, in particular with the medical use of opioids. Some of these barriers involve healthcare system issues, such as low institutional priority of pain relief and inadequacies in professional training and clinical practices; others stem from the stigma associated with drug abuse. Impediments in controlled substances and professional practice policies, both real and perceived, can interfere with the prescribing and dispensing of opioid analgesics and, ultimately, patient access to pain relief.

In 2000, the Pain & Policy Studies Group (PPSG) published findings from the first evaluation of federal and state pain policies, entitled *Achieving Balance: A Guide to Evaluation of Federal and State Policies (Evaluation Guide 2000)*. These findings were the result of a policy analysis based on the Central Principle of *balance*. The principle of *balance* is fundamental to international and national drug control policy and asserts that efforts to prevent abuse of opioid analgesics, while necessary, should not interfere with medical practice and patient care. Balanced policy recognizes the legitimacy of controlled substances prescribing for pain management. The PPSG developed 17 criteria that were used to identify policy provisions with the potential to either enhance or impede patient access to opioid analgesics (called “positive provisions” and “negative provisions” respectively; see [Section II](#) for more information). A team of policy analysts used these criteria to assess federal and state policies. The evaluation results were presented for each state, showing each positive and negative provision that was identified.

Since 2000, a number of states have modified their pain policies, making use of a model policy prepared by the Federation of State Medical Boards of the U.S. ([Appendix A](#)), as well as suggestions from the *Evaluation Guide 2000*. In order to document the changes that were made during the three-year period, the PPSG updated its policy database through March 2003, evaluated all new or amended policies, and published this, the second edition of the *Evaluation Guide (Evaluation Guide 2003)*. The methodology for the *Evaluation Guide 2003* is substantially the same as the first. The *Evaluation Guide 2003* presents the results of the second evaluation of federal and state policies, as well as more recent examples of positive policy language and models that can be used to improve state policies even further.

The *Evaluation Guide 2003* is being published concurrently with a *Progress Report Card*, that

quantifies the *Evaluation Guide 2003* results, grades each state's policy environment, and describes the changes in state pain policy between 2000 and 2003.

There can be pitfalls and unintended consequences in reforming pain policy. Changes in policy can advance or retard progress, depending on the content of the policy and the extent of collaboration among stakeholders during policy development. Policy change with no implementation or communication, even when the policy's message is positive, may have little value. Policy change aimed at the health professions and improving practice should be accompanied by a sustained commitment to repeated dissemination and incorporation into effective professional education. A state's policy should not only be balanced, but also *understood* as balanced, and efforts should be made to conform healthcare education to the elements of balanced policy.

The *Evaluation Guide 2003* is not a statement of a "position." Rather, it is the result of systematic policy analysis. While recognizing that states take different approaches to policy formulation, we assert that the overall goal is to improve the regulatory environment for pain management by developing balanced policies. The intent of this effort is to inform state and national policy discussions that lead to more balanced and consistent pain policy. As an increasing number of individuals and organizations examine the policy interface between the "war on drugs" and efforts to relieve pain, it is our hope that they will make use of the *Progress Report Card*, the *Evaluation Guide 2003*, and the many other relevant resources to which links are provided.

The PPSG is grateful to the Robert Wood Johnson Foundation for providing resources to accomplish this project.

CALIFORNIA

POLICIES EVALUATED

Statutes

UNIFORM CONTROLLED SUBSTANCES ACT

Health and Safety Code; Division 10. Uniform Controlled Substances Act

MEDICAL PRACTICE ACT

Business and Professions Code; Division 2. Healing Arts; Chapter 5. Medicine

PHARMACY PRACTICE ACT

Business and Professions Code; Division 2. Healing Arts; Chapter 9. Pharmacy

INTRACTABLE PAIN TREATMENT ACT (*Part of the Medical Practice Act*)

Business and Professions Code; Division 2. Healing Arts; Chapter 5. Medicine; Section 2241.5

HEALTH AND SAFETY CODE

Health and Safety Code; Division 2. Licensing Provisions; Chapter 5. Health Facilities; Article 1. General

PAIN PATIENT'S BILL OF RIGHTS

Health and Safety Code; Division 106. Personal Health Care; Part 4.5

EFFECT ON INTRACTABLE PAIN TREATMENT ACT; BILL OF RIGHTS

Health and Safety Code; Division 106. Personal Health Care; Part 4.5

Regulations

CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)

Title 16. Professional and Vocational Regulations; Division 17. California State Board of Pharmacy; Article 6. Dangerous Drugs

MEDICAL BOARD REGULATIONS (*No provisions found*)

Title 16. Professional and Vocational Regulations; Division 13. Medical Board of California

PHARMACY BOARD REGULATIONS (*No provisions found*)

Title 16. Professional and Vocational Regulations; Division 17. California State Board of Pharmacy

Other Governmental Policies

MEDICAL BOARD POLICY STATEMENT

California Medical Board. "A Statement by the Medical Board." *Action Report*, Vol. 50, pp. 4-5. July 1994.

MEDICAL BOARD GUIDELINE

California Medical Board. "Guideline for Prescribing Controlled Substances for Intractable Pain." *Action Report*, Vol. 51, pp. 1 and 8. October 1994. Adopted: May 6, 1994.

PHARMACY BOARD POLICY STATEMENT

California Pharmacy Board. "Dispensing Controlled Substances for Pain." *Health Notes - Pain Management*, Vol. 1, No. 1. 1996.

CALIFORNIA

PROVISIONS THAT MAY ENHANCE PAIN MANAGEMENT

	1	2	3	4	5	6	7	8
Criteria	Controlled substances are necessary for public health	Pain management is part of medical practice	Opioids are part of professional practice	Encourages pain management	Addresses fear of regulatory scrutiny	Prescription amount alone does not determine legitimacy	Physical dependence or analgesic tolerance are not confused with "addiction"	Other provisions that may enhance pain management
STATUTES								
Controlled Substances Act			•	•				•
Medical Practice Act								•
Pharmacy Practice Act ¹								
Intractable Pain Treatment Act		•	•		•			
Health and Safety Code				•				
Pain Patient's Bill of Rights		•						•
Effect on IPTA								•
REGULATIONS								
Controlled Substances ¹								
Medical Board ¹								
Pharmacy Board ¹								
OTHER GOVERNMENTAL POLICIES								
Medical Board Policy Statement		•	•	•	•	•	•	•
Medical Board Guideline		•	•	•	•			
Pharmacy Board Policy Statement			•	•		•	•	

Note: A dot indicates that one or more provisions were identified

¹ No provisions were found in this policy

CALIFORNIA

PROVISIONS THAT MAY IMPEDE PAIN MANAGEMENT

	9	10	11	12	13	14	15	16	17
Criteria	Opioids are a last resort	Implies opioids are not part of professional practice	Perpetuates belief that opioids hasten death	Physical dependence or analgesic tolerance confused with "addiction"	Medical decisions are restricted	Length of prescription validity is restricted	Practitioners are subject to additional prescription requirements	Other provisions that may impede pain management	Provisions that are ambiguous
STATUTES									
Controlled Substances Act					•	•	•	•	•
Medical Practice Act					•				•
Pharmacy Practice Act									•
Intractable Pain Treatment Act		•			•				•
Health and Safety Code ¹									
Pain Patient's Bill of Rights ¹									
Effect on TPLA								•	•
REGULATIONS									
Controlled Substances ¹									
Medical Board ¹									
Pharmacy Board ¹									
OTHER GOVERNMENTAL POLICIES									
Medical Board Policy Statement ¹									
Medical Board Guideline					•				•
Pharmacy Board Policy Statement ¹									

Note: A dot indicates that one or more provisions were identified

¹ No provisions were found in this policy



CRITERION 13a: [-]
*Medical decisions are
restricted
(Restrictions based on
patient characteristics)*



STATUTES
Controlled Substances Act

Cal Health & Saf Code § 11156

§ 11156. Prohibited prescription for, or dispensation to, addict, etc.

No person shall prescribe for or administer, or dispense a controlled substance to an addict or habitual user, or to any person representing himself as such, except as permitted by this division.



STATUTES

Controlled Substances Act

Cal Health & Saf Code § 11159.2

§ 11159.2. Prescriptions for terminally ill patients

(a) Notwithstanding any other provision of law, a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall not be subject to Section 11164.

(b) (1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. The signature, date, and information required by this paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed, as provided in paragraph (3) of subdivision (b) of Section 11164, and shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber, as provided in paragraph (2) of subdivision (b) of Section 11164.

(3) The prescription shall also indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(c) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (3) of subdivision (b), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(d) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

NOTES: NOTE-

Stats 1998 ch 789 provides:

SECTION 1. (a) The Legislature finds and declares the following:

(1) Although most, if not all, cancer pain can be relieved, a significant number of cancer patients with pain are inadequately treated, and some cancer patients die with severe, unrelieved pain.

(2) The mainstay of cancer pain management is opioid therapy, which therapy utilizes controlled substances classified in Schedule II.

(3) A prescription form for a Schedule II controlled substance is required to be prepared in triplicate, and the original is required to be sent to the Department of Justice.

(4) The Appropriate Prescribing Task Force of the Medical Board of California has recognized that pain is undertreated in California in part due to physicians' concern about undergoing investigation for overprescribing.

(5) Forty-five states in the nation have no requirement for triplicate prescriptions.

(6) Schedule II controlled substances would be prescribed more for the treatment of pain if prescription forms were not required to be sent to the Department of Justice.

(b) It is the intent of the Legislature, by the enactment of this act, to reduce the undertreatment of pain with the appropriate and legal prescribing of Schedule II controlled substances for terminally ill patients in order to relieve their pain and suffering.

CRITERION 17: [-]

Provisions that are ambiguous

Comment: It is unusual to create an exception to a statutory requirement in order to establish new requirements and a standard of care only for excepted patient groups.

CRITERION 8: [+]

Other provisions that may enhance pain management

Comment: The exemption of these patients from special prescription requirements nevertheless continues those requirements for all other patients.

CRITERION 5: [+]

Addresses fear of regulatory scrutiny

Comment: California legislation acknowledges that the triplicate prescription program is an impediment to the treatment of pain.

CRITERION 3: [+]
Opioids are part of professional practice

CRITERION 4: [+]
Encourages pain management

STATUTES

Controlled Substances Act

Cal Health & Saf Code § 11161

§ 11161. Issuance and nontransferability of prescription blanks; Unlawful possession; Felony violations by practitioners

CRITERION 15:
Additional prescription requirements

[-]

(a) Prescription blanks shall be issued by the Department of Justice in serially numbered groups of not more than 100 forms each in triplicate unless a practitioner orally, electronically, or in writing requests a larger amount, and shall be furnished to any practitioner authorized to write a prescription for controlled substances classified in Schedule II. The Department of Justice may charge a fee for the prescription blanks sufficient to reimburse the department for the actual costs associated with the preparation, processing, and filing of any forms issued pursuant to this section. The prescription blanks shall not be transferable. Any person possessing a triplicate prescription blank otherwise than as provided in this section is guilty of a misdemeanor. . . .
Cal Health & Saf Code § 11165 (2003)

§ 11165. (Operative until July 1, 2008; Repealed January 1, 2009) CURES project for electronic monitoring of prescription drugs

(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, establish the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. CURES shall be implemented as a pilot project, commencing on July 1, 1997, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies between the two systems.

NOTE-

Stats 1996 ch 738 provides:

SECTION 1. Recognizing that prescription drugs constitute the largest growing source of street drugs in the United States, the Legislature in 1992 approved Senate Concurrent Resolution 74 which convened a Controlled Substance Prescription Advisory Council to evaluate California's current triplicate prescription process for monitoring Schedule II controlled substances. The Legislature supports the council's findings that the ability to closely monitor the prescribing and dispensing of Schedule II controlled substances is essential to effectively control the abuse and diversion of these controlled substances. The Legislature agrees that electronic monitoring appears to offer a more effective method of tracking the prescribing and dispensing of these controlled substances with less intrusion into the legitimate prescribing and dispensing process than experienced by the current triplicate prescription process. However, until an electronic monitoring system is proven effective, the Legislature finds that sufficient cause does not yet exist to eliminate the existing triplicate prescription process.

It is the intent of the Legislature that this electronic monitoring system, the Controlled Substance Utilization Review and Evaluation System (CURES), be capable of providing complete, accurate, and timely data to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. It is the intent of the Legislature that the authorization granted pursuant to this act be used to establish CURES as a three-year pilot project for Schedule II controlled substances, to be administered concurrently with the existing triplicate prescription process, for the purpose of examining comparative efficiencies between the two systems. It is the intent of the Legislature that no new appropriation from the General Fund shall be made to create or maintain CURES.

CRITERION 8:
Other provisions that may enhance pain management

[+]

Comment: A pilot project has been established to study the feasibility of replacing the current triplicate prescription form with a less burdensome program.



CRITERION 14: [-]
*Length of prescription
validity is restricted*

STATUTES
Controlled Substances Act

Cal Health & Saf Code § 11166

§ 11166. When filling prescription for controlled substance is prohibited

No person shall fill a prescription for a controlled substance classified in Schedule II 14 or more days after the date written on the prescription by the prescriber. No person shall knowingly fill a mutilated or forged or altered prescription for a controlled substance except for the addition of the address of the person for whom the controlled substance is prescribed as provided by paragraph (3) of subdivision (b) of Section 11164.

CRITERION 16: [-]
*Other provisions that may
impede pain management*

Comment: Although institutional review of research is common, state controlled substances statutes governing research with controlled substances are not. Under federal and most state laws, physicians who are licensed to practice medicine and who have a DEA number are authorized to conduct research with the controlled substances which they are authorized to prescribe. California requires an additional approval from the Research Advising Panel, which may place an additional burden on clinical research needed for the development of new pain medications.

STATUTES
Controlled Substances Act

Cal Health & Saf Code § 11213

§ 11213. Lawful obtaining and using substances for research, instruction, or analysis

Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.



CRITERION 17: [-]
Provisions that are ambiguous

Comment: "Clearly excessive" implies there is a limit, but the limit is not specified.

STATUTES
Medical Practice Act

Cal Bus & Prof Code § 725

§ 725. Excessive prescribing or treatment; Treatment for intractable pain

Repeated acts of clearly excessive prescribing or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, or optometrist. However, pursuant to Section 2241.5, no physician and surgeon in compliance with the California Intractable Pain Treatment Act shall be subject to disciplinary action for lawfully prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars (\$100) nor more than six hundred dollars (\$600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both the fine and imprisonment.

STATUTES
Medical Practice Act

Cal Bus & Prof Code § 2241

§ 2241. Furnishing drugs to addict

Unless otherwise provided by this section, the prescribing, selling, furnishing, giving away, or administering or offering to prescribe, sell, furnish, give away, or administer any of the drugs or compounds mentioned in Section 2239 to an addict or habitue constitutes unprofessional conduct.

If the drugs or compounds are administered or applied by a licensed physician and surgeon or by a registered nurse acting under his or her instruction and supervision, this section shall not apply to any of the following cases:

- (a) Emergency treatment of a patient whose addiction is complicated by the presence of incurable disease, serious accident or injury, or the infirmities attendant upon age.
- (b) Treatment of addicts or habitues in state licensed institutions where the patient is kept under restraint and control, or in city or county jails or state prisons.
- (c) Treatment of addicts as provided for by Section 11217.5 of the Health and Safety Code.

CRITERION 17: [-]
Provisions that are ambiguous

Comment: It is unusual to create a regulatory exception in order to establish new requirements and a standard of care only for excepted patient groups.

CRITERION 13a: [-]
Medical decisions are restricted (Restrictions based on patient characteristics)

Comment: Despite the exceptions, the status of prescribing opioids for addicts remains unclear.

CRITERION 8: [+]
Other provisions that may enhance pain management

Comment: This exception does not apply to all patients with pain.



STATUTES
Pharmacy Practice Act

Cal Bus & Prof Code § 4301

§ 4301. Unprofessional conduct, procuring license by fraud or misrepresentation, or issuance of license by mistake

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

- (a) Gross immorality.
- (b) Incompetence.
- (c) Gross negligence.
- (d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

CRITERION 17:
Provisions that are
ambiguous

[-]

Comment: "Clearly excessive" implies there is a limit, but the limit is not specified.

STATUTES

Intractable Pain Treatment Act

Cal Bus & Prof Code § 2241.5

§ 2241.5. Administration of controlled substances to person experiencing "intractable pain"

(a) Notwithstanding any other provision of law, a physician and surgeon may prescribe or administer controlled substances to a person in the course of the physician and surgeon's treatment of that person for a diagnosed condition causing intractable pain.

(b) "Intractable pain," as used in this section, means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.

(c) No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

(d) This section shall not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances.

(e) This section shall not authorize a physician and surgeon to prescribe or administer controlled substances to a person the physician and surgeon knows to be using drugs or substances for nontherapeutic purposes.

(f) This section shall not affect the power of the board to deny, revoke, or suspend the license of any physician and surgeon who does any of the following:

(1) Prescribes or administers a controlled substance or treatment that is nontherapeutic in nature or nontherapeutic in the manner the controlled substance or treatment is administered or prescribed or is for a nontherapeutic purpose in a nontherapeutic manner.

(2) Fails to keep complete and accurate records of purchases and disposals of substances listed in the California Controlled Substances Act, or of controlled substances scheduled in, or pursuant to, the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. A physician and surgeon shall keep records of his or her purchases and disposals of these drugs, including the date of purchase, the date and records of the sale or disposal of the drugs by the physician and surgeon, the name and address of the person receiving the drugs, and the reason for the disposal of or the dispensing of the drugs to the person and shall otherwise comply with all state recordkeeping requirements for controlled substances.

(3) Writes false or fictitious prescriptions for controlled substances listed in the California Controlled Substances Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(4) Prescribes, administers, or dispenses in a manner not consistent with public health and welfare controlled substances listed in the California Controlled Substance Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(5) Prescribes, administers, or dispenses in violation of either Chapter 4 (commencing with Section 11150) or Chapter 5 (commencing with Section 11210) of Division 10 of the Health and Safety Code or this chapter.

(g) Nothing in this section shall be construed to prohibit the governing body of a hospital from taking disciplinary actions against a physician and surgeon, as authorized pursuant to Sections 809.05, 809.4, and 809.5.

CRITERION 2: *Pain management is part of medical practice* **[+]**

CRITERION 17: *Provisions that are ambiguous* **[-]**

Comment: Does this imply that opioids are a treatment of last resort?

CRITERION 5: *Addresses fear of regulatory scrutiny* **[+]**

CRITERION 3: *Opioids are part of professional practice* **[+]**

CRITERION 10: *Implies opioids are not part of professional practice* **[-]**

CRITERION 13b: *Medical decisions are restricted (Mandated consultation)* **[-]**

CRITERION 13a: *Medical decisions are restricted (Restrictions based on patient characteristics)* **[-]**



STATUTES

Health and Safety Code

Cal Health & Saf Code § 1254.7

§ 1254.7. Pain assessment

(a) It is the intent of the Legislature that pain be assessed and treated promptly, effectively, and for as long as pain persists.

(b) Every health facility licensed pursuant to this chapter shall, as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken. The health facility shall ensure that pain assessment is performed in a consistent manner that is appropriate to the patient. The pain assessment shall be noted in the patient's chart in a manner consistent with other vital signs.

CRITERION 4:
Encourages pain
management

[+]

STATUTES

Pain Patient's Bill of Rights

California Health & Safety Code §124960

§ 124960. Legislative findings and declarations

The Legislature finds and declares all of the following:

- (a) The state has a right and duty to control the illegal use of opiate drugs.
- (b) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.
- (c) For some patients, pain management is the single most important treatment a physician can provide.
- (d) A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain.
- (e) Due to the complexity of their problems, many patients suffering from severe chronic intractable pain may require referral to a physician with expertise in the treatment of severe chronic intractable pain. In some cases, severe chronic intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.
- (f) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute and severe chronic intractable pain can be safe.
- (g) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.
- (h) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her severe chronic intractable pain.
- (i) A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain as long as the prescribing is in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.
- (j) A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as the prescribing is in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.
- (k) The patient's physician may refuse to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

CRITERION 2: [✓]
Pain management is part of medical practice

CRITERION 3: [✓]
Other provisions that may enhance pain management

Comment: This provision recognizes the need for increased communication between healthcare practitioners

CRITERION 8: **[+]**
Other provisions that may enhance pain management

Comment: Sections (a) and (b) recognize the patient's right to choose or refuse different types of treatments.

CRITERION 17: **[-]**
Provisions that are ambiguous

Comment: It appears that the Pain Patient's Bill of Rights requires that all opiate treatment for patients with "severe chronic intractable pain," must be according to the IPTA, thus requiring an evaluation by a second physician in every case, and excluding certain patient populations. Also, is it legal for a physician to prescribe medically necessary dosages of opioids for patients with severe chronic pain who are not qualified under the IPTA?

STATUTES

Effect on Intractable Pain Treatment Act; Bill of Rights

California Health & Safety Code §124961

§ 124961. Effect on Intractable Pain Treatment Act; Bill of Rights

Nothing in this section shall be construed to alter any of the provisions set forth in the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code. This section shall be known as the Pain Patient's Bill of Rights.

(a) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her severe chronic intractable pain.

(b) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve severe chronic intractable pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(c) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

(d) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain, as long as that prescribing is in conformance with the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(e) A patient may voluntarily request that his or her physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

(f) Nothing in this section shall do either of the following:

(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in the Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code, or the regulations adopted thereunder.

(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

CRITERION 17: **[-]**
Provisions that are ambiguous

Comment: The phrase "severe chronic intractable pain" is used throughout this policy. The intended result of such elaborate and unconventional medical terminology is unclear, but appears to limit the patient population which should be given access to "proper treatment" of pain, including the use of opioids, and which is given the option to request or reject any treatments. What is the effect of this law on patients with pain that is not severe, chronic, or intractable? Is there a greater risk of discipline for a physician who would prescribe opioids to a patient with pain which was not severe, chronic, or intractable?

CRITERION 17: **[-]**
Provisions that are ambiguous

Comment: This provision may be confusing, and even in conflict, when considered in conjunction with provision §124960(g) which states that patients qualify for opiate treatment after "other means of treatment;" in §124961(b) the patient does not have to "submit" to certain treatments.

CRITERION 16: **[-]**
Other provisions that may impede pain management

Comment: Allowing a physician to refuse to prescribe opiate medications would appear to conflict with criteria that recognize that opioids are necessary for public health and are part of medical practice. Furthermore, how does this qualify as a "Pain Patient's Bill of Rights" if a physician may refuse to provide opiate analgesics to a patient in pain?

Without commenting on the concept of patients' bills of rights, this language would fall short of providing any rights and thus may establish a false expectation for adequate pain management.



OTHER GOVERNMENTAL POLICY

Medical Board Statement

A STATEMENT BY THE MEDICAL BOARD

INTRODUCTION

The 1993 report of the Medical Board to the Governor signaled a new beginning in the history of medical regulation in California. An important part of this initiative is implementation of the recommendations made by the Board's Task Force on Appropriate Prescribing, chaired by Jacqueline Trestrall, M.D.

The Task Force was established to look into "malprescribing," one of the fastest growing categories of physician discipline. The Board continues to be concerned that controlled substances are subject to abuse by individuals who seek them for their mood altering and other psychological effects, rather than for legitimate medical purposes.

CRITERION 4:
Encourages pain management

[+]

The Board is also concerned about effective pain management and the appropriate medical use of controlled substances. During the Task Force's public meetings, the members heard testimony that some physicians avoid prescribing controlled substances, including the "triplicate" drugs, for patients with intractable pain for fear of discipline by the Board. The Task Force recommended that the Board take a pro-active approach to emphasize to all California physicians that it supports prescribing of opioid analgesics (narcotics) and other controlled substances when medically indicated for the treatment of pain, including intractable pain. After careful review of this matter, the Board concurs with the following statement.

CRITERION 3:
Opioids are part of professional practice

[+]

This statement is consistent with good medical practice, protection of public health and consumer interests, with international treaties, federal and California law, including the California Intractable Pain Treatment Act.

THE PAIN PROBLEM

The Board recognizes that pain, whether due to trauma, surgery, cancer and other diseases, is often undertreated. Minorities, women, children, the elderly and people with HIV/AIDS are at particular risk for under treatment of their pain. Unrelieved pain has a harsh and sometimes disastrous impact on the quality of life of people and their families.

While some progress is being made to improve pain and symptom management, the Board is concerned that a number of factors continue to interfere with effective pain management. These include the low priority of pain management in our health care system, incomplete integration of current knowledge into medical education and clinical practice, lack of knowledge among consumers about pain management, exaggerated fears of opioid side effects and addiction, and fear of legal consequences when controlled substances are used.

CRITERION 2:
Pain management is part of medical practice

[+]

PAIN MANAGEMENT SHOULD BE A HIGH PRIORITY IN CALIFORNIA

Principles of quality medical practice dictate that citizens of California who suffer from pain should be able to obtain the relief that is currently available. The Board believes that the appropriate application of current knowledge and treatments would greatly improve the quality of life for many California citizens, and could also reduce the morbidity and the costs that are associated with uncontrolled pain.

In addition to making this statement, the Board will take a number of steps to help make effective pain management a reality in California. The Board has provided information to all state physicians about new clinical practice guidelines for pain management that have been prepared by a panel of experts supported by the Agency for Health Care Policy and Research. The Board also co-sponsored and participated in the March 18, 1994 Pain Management and Appropriate Prescribing Summit in conjunction with the Department of Consumer Affairs on removing impediments to appropriate prescribing of controlled substances for effective pain management. Further, the Board will develop guidelines to help physicians avoid investigation if they appropriately prescribe controlled substances for pain management.

Prescribing Controlled Substances for Pain

THE APPROPRIATE ROLE OF OPIOID ANALGESICS

There are numerous drug and non-drug treatments that are used for the management of pain and other symptoms. The proper treatment of any patient's pain depends upon a careful diagnosis of the etiology of the pain, selection of appropriate and cost-effective treatments, and ongoing evaluation of the results of treatment. Opioid analgesics and other controlled substances are useful for the treatment of pain, and are considered the cornerstone of treatment of acute pain due to trauma, surgery and chronic pain due to progressive diseases such as cancer. Large doses may be necessary to control pain if it is severe. Extended therapy may be necessary if the pain is chronic.

(CONTINUED ON THE NEXT PAGE)

OTHER GOVERNMENTAL POLICIES

Medical Board Statement

(CONTINUED)

The Board recognizes that opioid analgesics can also be useful in the treatment of patients with intractable non-malignant pain especially where efforts to remove the cause of pain or to treat it with other modalities have failed. The pain of such patients may have a number of different etiologies and may require several treatment modalities. In addition, the extent to which pain is associated with physical and psychosocial impairment varies greatly. Therefore, the selection of a patient for a trial of opioid therapy should be based upon a careful assessment of the pain as well as the disability experienced by the patient. Continuation of opioid therapy should be based on the physician's evaluation of the results of treatment, including the degree of pain relief, changes in physical and psychological functioning, and appropriate utilization of health care resources. Physicians should not hesitate to obtain consultation from legitimate practitioners who specialize in pain management.

The Board recommends that physicians pay particular attention to those patients who misuse their prescriptions, particularly when the patient or family have a history of substance abuse that could complicate pain management. The management of pain in such patients requires extra care and monitoring, as well as consultation with medical specialists whose area of expertise is substance abuse or pain management.

CRITERION 7: [+]
Physical dependence or analgesic tolerance are not confused with "addiction"

The Board believes that addiction should be placed into proper perspective. Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a behavioral syndrome characterized by psychological dependence and aberrant drug-related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts or habitues merely because they are being treated with opioids.

PAIN MANAGEMENT, CONTROLLED SUBSTANCES AND THE LAW

The laws and regulations of the federal government and the State of California impose special requirements for the prescribing of controlled substances, including requirements as to the form of the prescription document, so as to prevent harm to the public health that is caused when prescription drugs are diverted to non-medical uses. For example, it is illegal to prescribe controlled substances solely to maintain narcotic addiction. However, federal and California law clearly recognize that it is a legitimate medical practice for physicians to prescribe controlled substances for the treatment of pain, including intractable pain.

The Medical Board will work with the Drug Enforcement Administration, the Bureau of Narcotic Enforcement, the Office of the Attorney General, the Board of Pharmacy and its own investigators in an attempt to develop policy and guidelines based on the physician's diagnosis and treatment program rather than amounts of drugs prescribed.

Concerns about regulatory scrutiny should not make physicians who follow appropriate guidelines reluctant to prescribe or administer controlled substances, including Schedule II drugs, for patients with a legitimate medical need for them. A physician is not subject to Board action when prescribing in the regular course of his or her profession to one under the physician's treatment for a pathology or condition and where the prescription is issued after a good faith examination and where there is medical indication for the drug. Good faith prescribing requires an equally good faith history, physical examination and documentation.

CRITERION 6: [+]
Prescription amount alone does not determine legitimacy

The Medical Board may identify a pattern of controlled substance use that merits further examination. A private, courteous and professional inquiry can usually determine whether the physician is in good faith appropriately prescribing for patients, or whether an investigation is necessary. The Board will judge the validity of prescribing based on the physician's diagnosis and treatment of the patient and whether the drugs prescribed by the physician are appropriate for that condition, and will not act on the basis of predetermined numerical limits on dosages or length of drug therapy.

The Board hopes to replace practitioners' perception of inappropriate regulatory scrutiny with recognition of the Board's commitment to enhance the quality of life of patients by improving pain management while, at the same time, preventing the diversion and abuse of controlled substances.

CRITERION 5: [+]
Addresses fear of regulatory scrutiny

CRITERION 8: [+]
Other provisions that may enhance pain management

Comment: This provision reflects the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

OTHER GOVERNMENTAL POLICIES

Medical Board Guideline

GUIDELINE FOR PRESCRIBING CONTROLLED SUBSTANCES
FOR INTRACTABLE PAIN

PREAMBLE

On May 6, 1994, the Medical Board of California formally adopted a policy statement entitled "Prescribing controlled substances for pain." (Action Report, July 1994) The statement outlines the Board's proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement is the product of a year of research, hearings and discussions. California physicians are encouraged to consult the policy statement and these guidelines.

The Medical Board recognizes that inappropriate prescribing of controlled substances including the opioids can lead to drug abuse and diversion. Inappropriate prescribing can also lead to ineffective management of pain, unnecessary suffering of patients and increased health care costs. The Board recognizes that some physicians do not treat pain properly due to lack of knowledge or concern about pain. Fear of discipline by the Board may also be an impediment to medically appropriate prescribing for pain. This Guideline is intended to encourage effective pain management in California and help physicians reach a level of comfort about appropriate prescribing by clarifying the principles of professional practice that are endorsed by the Board.

CRITERION 5:
*Addresses fear of
regulatory scrutiny*

[+]

CRITERION 4:
*Encourages pain
management*

[+]

CRITERION 2:
*Pain management is
part of medical practice*

[+]

"A HIGH PRIORITY"

The Board strongly urges physicians to view effective pain management as a high priority in all patients, including children and the elderly. Pain should be assessed and treated promptly, effectively and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain, pain assessment and pain treatment. Pain treatment may involve the use of several drug and non-drug treatment modalities, often in combination. For some types of pain the use of drugs is emphasized and should be pursued vigorously; for other types, the use of drugs is better de-emphasized in favor of other therapeutic modalities. Physicians should have sufficient knowledge or consultation to make such judgments for their patients.

Drugs, in particular the opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures, and cancer. Physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines which have been endorsed by the Board as a sound yet flexible approach to the management of these types of pain.

CRITERION 17:
*Provisions that are
ambiguous*

[+]

*Comment: Does this imply
that opioids are a treatment
of last resort?*

CRITERION 3:
*Opioids are part of
professional practice*

[+]

The prescribing of opioid analgesics for other patients with intractable non-cancer pain may also be beneficial, especially when efforts to remove the cause of pain or to treat it with other modalities have been unsuccessful.

Intractable pain is defined by law in California as: "a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain." (Section 2241.5(b) California Business and Professions Code)

Physicians who prescribe opioids for intractable pain should not fear disciplinary action from any enforcement or regulatory agency in California if they follow California law (section 2241.5 (c)), which reads, "No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain." Also, physicians should use sound clinical judgment, and care for their patients according to the following principles of responsible professional practice:

(CONTINUED ON NEXT PAGE)



OTHER GOVERNMENTAL POLICIES

Medical Board Guideline

NEW, EASY GUIDELINES ON PRESCRIBING

1. HISTORY/PHYSICAL EXAMINATION

A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function, substance abuse history, assessment of underlying or coexisting diseases or conditions, and should also include the presence of a recognized medical indication for the use of a controlled substance. Prescribing controlled substances for intractable pain in California as noted in the definition in the text of the Report, also requires evaluation by one or more specialists.

2. TREATMENT PLAN; OBJECTIVES

The treatment plan should state objectives by which treatment success can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician should tailor drug therapy to the individual medical needs of each patient. Several treatment modalities or a rehabilitation program may be necessary if the pain has differing etiologies or is associated with physical and psychosocial impairment.

3. INFORMED CONSENT

The physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian.

4. PERIODIC REVIEW

The physician should periodically review the course of opioid treatment of the patient and any new information about the etiology of the pain. Continuation or modification of opioid therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient has not improved, the physician should assess the appropriateness of continued opioid treatment or trial of other modalities.

5. CONSULTATION

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

6. RECORDS

The physician should keep accurate and complete records according to items 1-5 above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, agreements with the patient, and periodic reviews.

7. COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS AND REGULATIONS

To prescribe controlled substances, the physician must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions.

POSTSCRIPT

Under federal and state law, it is unlawful for a physician to prescribe controlled substances to a patient for other than a legitimate medical purpose (for example, prescribing solely for the maintenance of opioid addiction), or outside of professional practice (for example, prescribing without a medical examination of the patient).

It is lawful to prescribe opioid analgesics in the course of professional practice for the treatment of intractable pain according to federal regulations and California Business and Professions Code Section 2241.5, the California Intractable Pain Treatment Act (CIPTA). However, the CIPTA does not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances (Section 2241.5(d)), and does not authorize a physician or surgeon to prescribe or administer controlled substances to a person the practitioner knows to be using drugs or substances for nontherapeutic purposes (Section 2241.5(e)).

THE MISSION OF THE MEDICAL BOARD OF CALIFORNIA

The mission of the Medical Board of California is to protect consumers through proper licensing of physicians and surgeons and certain allied health professions and through the vigorous, objective enforcement of the Medical Practice Act.

CRITERION 13b:
Medical decisions are
restricted
(Mandated consultation)



OTHER GOVERNMENTAL POLICIES

Pharmacy Board Policy Statement

DISPENSING CONTROLLED SUBSTANCES FOR PAIN

INTRODUCTION

Healthcare leaders and patient advocates from throughout California met at the Summit on Effective Pain Management: Removing Impediments to Appropriate Prescribing in Los Angeles in 1994 to discuss the effective management of pain. Summit participants concurred that effective pain management, including the use of controlled substance medications, is essential to the health and welfare of Californians experiencing pain. It was also concluded that inappropriate or undertreatment of pain is serious and wide spread.

In response to these findings, the California State Board of Pharmacy is taking a leadership role in promoting the effective management of pain for the state's citizens. The Board's objectives include educating pharmacists on advances in appropriate pain management and taking active roles in providing this therapy. The Board is working to computerize the triplicate prescription program; is encouraging the timely availability of opioids in different healthcare settings such as hospitals, patient's homes and pharmacies; and is encouraging better knowledge and attitudes of patients, the public and other licensed healthcare professionals in the use of pain medications-all with the goal of positively influencing the care of patients in pain.

CRITERION 4:
*Encourages pain
management*

[+]

The Board of Pharmacy must ensure that laws, regulations, policies, and practices promote the availability and use of controlled substance drugs to patients for legitimate pain management. The Board encourages programs to help educate patients, the public, and licensed healthcare professionals about the effective use of medications in the treatment of various types of pain. The Board also recognizes that, with proper assessment, therapeutic planning, and follow up, medications should be available and used when needed.

The pharmacist's role (as educator and manager) in providing drug therapy for patients in pain is extensive. If pharmacists are to provide complete pain management services, they must fulfill their responsibilities to:

1. Facilitate the dispensing of legitimate prescriptions;
2. Understand and learn about the effective uses of all pain medications, especially opioids and other controlled substances, in the management of pain;
3. Carefully explain dosage regimens, and discuss potential side effects of pain medications;
4. Monitor and assess the patient for effective pain therapy outcomes, evaluate compliance, assess for tolerance to opioids, and ensure subsequent dosage adjustments as needed;
5. Obtain, retain, and update appropriate information documenting the course of, and need for, on-going opioid therapy;
6. Encourage patients to talk with their pharmacist about their medications, the benefits and problems;
7. Discuss and allay patients' possible fear of addiction with the use of narcotics where this is a factor;
8. Watch for patients who misuse their prescriptions and be especially aware of a patient or family history of substance abuse that might complicate pain management and act accordingly;

(CONTINUED ON NEXT PAGE)

OTHER GOVERNMENTAL POLICIES

Pharmacy Board Policy Statement

(CONTINUED)

9. Assess the patient for adverse drug reactions from the pain therapy regimen and take action to minimize or eliminate them;
10. Be aware of and recommend non-medication treatments for pain or refer patients for such when appropriate;
11. Evaluate OTC, prescription drugs, and alcohol taken with pain medications for potential drug interactions;
12. Recognize that patients and caregivers are important sources of information in assessing the patient's pain therapy;
13. Act as a liaison between patients and other healthcare providers, ensuring that there is open communication and understanding about the drugs patients are taking to reduce pain; and
14. Optimize pain management so patients can reach their highest level of functioning and quality of life.

ROLE OF OPIOIDS IN PAIN MANAGEMENT

Many patients with cancer or chronic medical conditions experience moderate to severe pain that is often inappropriately treated or undermedicated. Pain can have a negative effect on the patient's health and quality of life resulting in needless suffering, emotional distress, loss of productivity and possibly slower recovery from illness, injury, and disease.

Although there have been significant advances in knowledge about pain and the use of opioids and other medications in pain management, many licensed healthcare professionals prescribe, dispense, or administer these medications suboptimally. There is a misconception by patients, the public, and some licensed healthcare providers that opioids are "bad" drugs because opioids are often associated with drug abuse, addiction, and criminal activity. Studies have shown that opioids used appropriately for pain management have an extremely low potential for abuse.

CRITERION 6: [-]
Prescription amount alone does not determine legitimacy

The Board understands that the ongoing use of opioids for cancer, post-surgical, and chronic pain is not what causes addiction or a patient's desire for higher doses of pain medication. Patients suffering from extreme pain or progression of disease may require increased doses of medication; the appropriate dose is that which is required to adequately treat the pain, even if the dose is higher than usually expected. In addition, with long-term treatment of pain with opioids, patients may develop a tolerance to the drug or a dependence on the drug. These occurrences are considered "normal" and "to be expected" - they should not be confused by the licensed healthcare professional with drug addiction or be mislabeled as "drug seeking."

CRITERION 7: [-]
Physical dependence or analgesic tolerance are not confused with "addiction"

The Board understands that an important part of effective pain management is ensuring that patients do not have difficulty obtaining adequate medication for pain relief. The Board recognizes that it is the professional responsibility of the pharmacist to recommend that patients in pain receive appropriate, timely, and adequate drug therapy to reduce their pain.

CRITERION 3: [-]
Opioids are part of professional practice

CONCLUSION

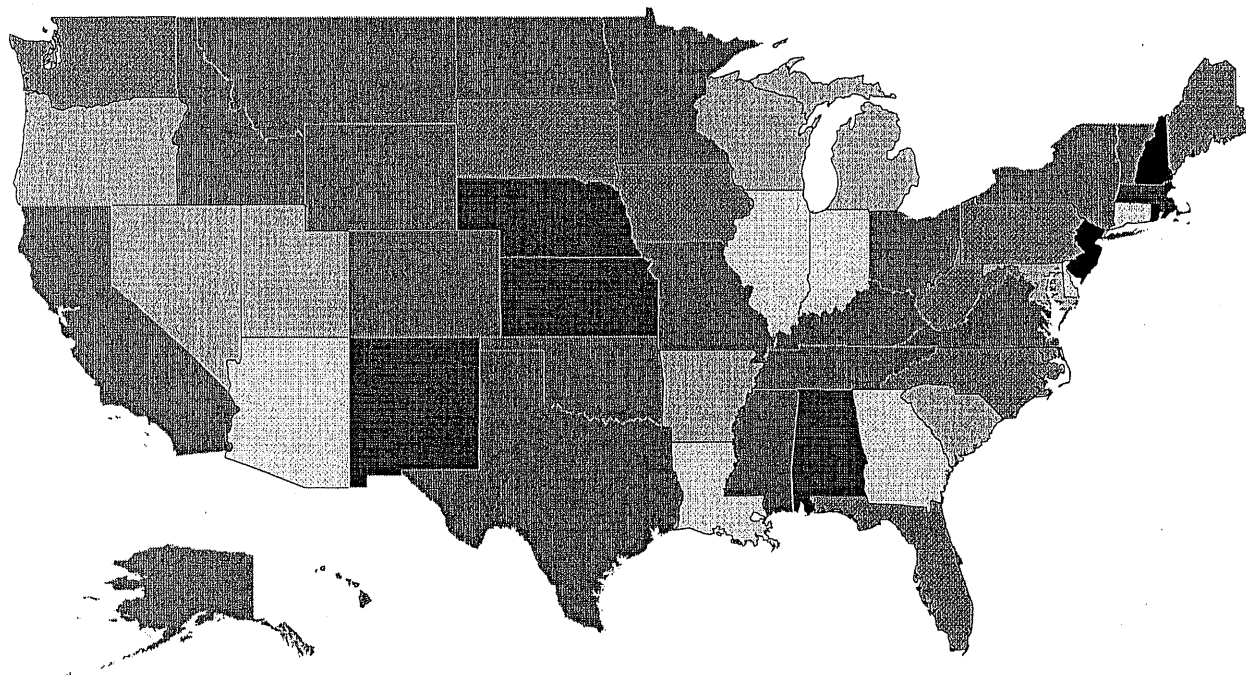
Recognition of the utility of opioids and other controlled substance drugs for the treatment of pain resulting from a variety of conditions is well established. The need for regulators and practitioners to understand this use, and to adopt laws, policies, and practices is self-evident if patients are to receive relief from pain which is now medically possible. In addition, pharmacists must understand their role in the on-going monitoring and assessment of patients' pain management. Working cooperatively, the Board of Pharmacy and the profession can ensure that opioids and other controlled substance drugs are used appropriately and effectively.

MAKING THE GRADE: HOW DO THE STATES RATE?

Grades for 2003

Figure 1:

States' grades for 2003 are presented in Figure 1 and Table 5.



A	B+	B	C+	C	D+	D	F
None	Alabama Kansas Nebraska Massachusetts New Mexico	Florida Iowa Maine North Carolina Pennsylvania South Dakota Washington West Virginia	Arkansas Maryland Michigan Nevada Oregon South Carolina Utah Wisconsin	Alaska California Colorado Idaho Kentucky Minnesota Mississippi Missouri Montana New York North Dakota Ohio Oklahoma Tennessee Texas Vermont Virginia Wyoming	Arizona Connecticut Delaware Dist. of Columbia Georgia Hawaii Illinois Indiana Louisiana	New Hampshire New Jersey Rhode Island	None

MAKING THE GRADE: HOW DO THE STATES RATE?

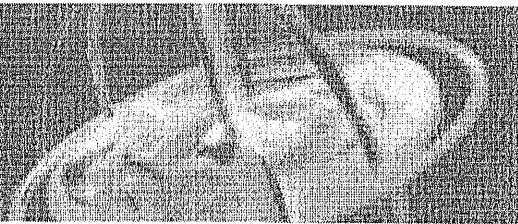
Table 5: State Grades for 2003

STATES	2003 GRADES	STATES	2003 GRADES
AL	B+	MT	C
AK	C	NE	B+
AZ	D+	NV	C+
AR	C+	NH	D
CA	C	NJ	D
CO	C	NM	B+
CT	D+	NY	C
DE	D+	NC	B
DC	D+	ND	C
FL	B	OH	C
GA	D+	OK	C
HI	D	OR	C+
ID	C	PA	B
IL	D+	RI	D
IN	D+	SC	C+
IA	B	SD	B
KS	B+	TN	C
KY	C	TX	C
LA	D+	UT	C+
ME	B	VT	C
MD	C+	VA	C
MA	B+	WA	B
MI	C+	WV	B
MN	C	WI	C+
MS	C	WY	C
MO	C		

Description of State Grades for 2003

- ◆ 35% of states scored around the average (thereby earning a grade of C), while 41% scored above the average and 24% fell below the average.
- ◆ No state received an A or F.
- ◆ A few regional patterns emerged: States in the central Midwest (Iowa, Kansas, Nebraska, and South Dakota) received Bs; the neighboring states of Illinois and Indiana, earned grades of D+; western states (California, Colorado, Idaho, Montana, Nevada, Oregon, Utah, and Wyoming) earned grades in the C range; the three states with the largest population (California, New York, and Texas) each earned average grades of C, owing to presence of policies containing many positive provisions but also a substantial number of negative provisions.

MAKING THE GRADE: HOW DO THE STATES RATE?



Changes from 2000 to 2003

To evaluate changes, either positive or negative, that occurred during the three-year period, 2003 grades were compared with the 2000 grades^h (see Table 6).

Table 6: State Grades, 2000 and 2003

STATES	2000 GRADES	2003 GRADES	STATES	2000 GRADES	2003 GRADES
AL	B+	B+	MT	C	C
AK	C	C	NE	B+	B+
AZ	D+	D+	NV	D	C+
AR	C+	C+	NH	D	D
CA	C	C	NJ	D	D
CO	C	C	NM	B	B+
CT	D+	D+	NY	C	C
DE	D+	D+	NC	B	B
DC	D+	D+	ND	C	C
FL	C+	B	OH	D+	C
GA	D+	D+	OK	C	C
HI	D	D+	OR	C+	C+
ID	D	C	PA	B	B
IL	D+	D+	RI	D	D
IN	D+	D+	SC	C	C+
IA	D+	B	SD	B	B
KS	B	B+	TN	D+	C
KY	D+	C	TX	C	C
LA	D+	D+	UT	C+	C+
ME	B	B	VT	C	C
MD	C+	C+	VA	C	C
MA	D+	B+	WA	B	B
MI	D+	C+	WV	C+	B
MN	C	C	WI	C	C+
MS	C	C	WY	C	C
MO	D	C			

Although no states received an A or F in either 2000 or 2003, a number of important changes occurred:

- ◆ 29% of states received above a C in 2000, increasing to 41% in 2003.
- ◆ 20 of 51 states (39%) changed their policies; the policy changes were sufficient in 16 of these states to produce a grade improvement.

^h 2000 grades were calculated to allow comparison and measure progress; see Method to Assign Grades section.

MAKING THE GRADE: HOW DO THE STATES RATE?

- ◆ Of the 16 states that improved, Massachusetts had the greatest improvement, moving from a D+ to a B+. This improvement was due to the Federation of State Medical Board's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Model Guidelines)*. States that fully adopt the *Model Guidelines* received the greatest number of positive provisions (7) from a single policy, with no negative provisions:

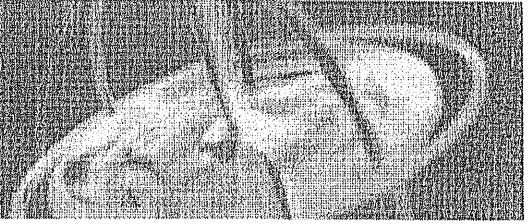
- Criterion #2: Pain management is recognized as part of general medical practice,
- Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
- Criterion #4: Pain management is encouraged,
- Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed,
- Criterion #6: Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
- Criterion #7: Physical dependence or analgesic tolerance are not confused with "addiction," and
- Criterion #8: Other provisions that may enhance pain management.

Table 7 identifies the states with positive, negative, and no policy change.

Table 7: Grade Change in State Pain Policy Between March 2000 and March 2003

Positive Change (16 states)	No Change (35 states)	
Florida	Alabama	New Hampshire
Hawaii	Alaska	New Jersey
Idaho	Arizona	New York
Iowa	Arkansas	North Carolina
Kansas	California	North Dakota
Kentucky	Colorado	Oklahoma
Massachusetts	Connecticut	Oregon
Michigan	Delaware	Pennsylvania
Missouri	District of Columbia	Rhode Island
Nevada	Georgia	South Dakota
New Mexico	Illinois	Texas
Ohio	Indiana	Utah
South Carolina	Louisiana	Vermont
Tennessee	Maine	Virginia
West Virginia	Maryland	Washington
Wisconsin	Minnesota	Wyoming
	Mississippi	
	Montana	
	Nebraska	

MAKING THE GRADE: HOW DO THE STATES RATE?



Reasons for the positive changes

The driving force behind the positive policy changes that occurred between 2000 and 2003 was state healthcare regulatory boards that adopted policies encouraging pain management or palliative care.

- ◆ Adoption of Model Guidelines: Six states (Kentucky, Massachusetts, Missouri, Nevada, New Mexico, and Texas) adopted healthcare regulatory policies based on the Federation of State Medical Board's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Model Guidelines)*. States that fully adopt the *Model Guidelines* received the greatest number of positive provisions (7) from a single policy, with no negative provisions:

- Criterion #2: Pain management is recognized as part of general medical practice,
- Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
- Criterion #4: Pain management is encouraged,
- Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed,
- Criterion #6: Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
- Criterion #7: Physical dependence or analgesic tolerance are not confused with "addiction," and
- Criterion #8: Other provisions that may enhance pain management.

Twenty-two states have adopted the *Model Guidelines* either in whole or in part.ⁱ

- ◆ Adoption of Pharmacy Board Policies: Iowa adopted a pharmacy board policy statement relating to pain management, which added four positive provisions:
 - Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
 - Criterion #4: Pain management is encouraged,
 - Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed, and
 - Criterion #8: Other provisions that may enhance pain management.
- ◆ Adoption of Joint Board Policies: Three states (Kansas, Montana, and West Virginia) approved a joint policy statement relating to the use of controlled substances for the treatment of pain, which was developed collaboratively by several regulatory boards such as medicine, pharmacy, and nursing; collectively, the following positive provisions were added:
 - Criterion #2: Pain management is recognized as part of general medical practice,
 - Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
 - Criterion #4: Pain management is encouraged
 - Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed,
 - Criterion #6: Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
 - Criterion #7: Physical dependence or analgesic tolerance are not confused with "addiction," and
 - Criterion #8: Other provisions that may enhance pain management.

ⁱ These states are Alabama, Arizona, Florida, Iowa, Kansas, Kentucky, Maine, Massachusetts, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, and West Virginia.

MAKING THE GRADE: HOW DO THE STATES RATE?



- ◆ Adoption of Palliative Care Policies: The Missouri medical board adopted a palliative care guideline to educate physicians about the treatment of terminally-ill patients, adding two positive provisions:

- Criterion #4: Pain management is encouraged, and
- Criterion #8: Other provisions that may enhance pain management.

Positive policy change also occurred when states repealed negative provisions.

- ◆ Change in Prescription Monitoring Programs: Three states (Hawaii, Idaho, and Michigan) repealed their requirement for a multiple- or single-copy prescription form (Criterion #15) and replaced it with an Electronic Data Transfer system that does not require a special government-issued prescription form. Such a change is thought to eliminate a barrier to pain management because of reluctance to obtain and use the forms and by being a less intrusive method to monitor physicians' prescribing. Only three states (California, New York, and Texas) currently have a multiple- or single-copy prescription form requirement.
- ◆ Repeal of Restrictive Prescription Validity Periods: Four states modified overly restrictive prescription validity periods (Criterion #14) from controlled substances statutes and/or regulations:
 - Hawaii eliminated its 3 day period;
 - Michigan eliminated a 5 day period;
 - Wisconsin eliminated a 7 day period; and
 - Idaho extended its validity period from 7 days to 30 days.

This change eliminates the barrier of an unrealistically short validity period (i.e., the number of days within which the prescription must be dispensed following its issue), which can make it difficult for a patient to obtain medications without having to make sometimes expensive arrangements, especially when travel, slow mail delivery, or other extenuating circumstances exist. Exceeding a prescription's validity period necessitates issuance of a new prescription and a likely return visit to the physician. Seven states have retained a validity period of less than two weeks.^j

- ◆ Repeal of Mandated Consultation Provision: Three states (Iowa, Massachusetts, and Michigan) repealed provisions mandating that physicians always consult with pain specialists when using controlled substances to treat patients with pain (Criterion #13.2). Such provisions typically require a physician treating chronic non-cancer pain with opioids to obtain "...[an] evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain..."⁵⁷ Although there is no question that physicians should seek consultation when needed, such a requirement may not be necessary for every case, especially if the practitioner is knowledgeable about pain management. In addition, such a requirement does not appear to allow for patients who need immediate treatment. Eleven states continue to mandate consultation under certain circumstances when using opioids to treat patients with pain.^k

^j These states are California, Delaware, Illinois, Nevada, Rhode Island, Texas, and Vermont.

^k These states are Arizona, California, Colorado, Idaho, Mississippi, Nevada, New York, Ohio, Oregon, Rhode Island, and Vermont.

MAKING THE GRADE: HOW DO THE STATES RATE?

Despite this positive change, a few states added more restrictive provisions.

- ◆ Adoption of Hastening Death Provisions: Ohio and Rhode Island added language that perpetuates the misconception that the therapeutic use of opioids to relieve pain in patients at the end of life hastens death (Criterion #11). For example, Rhode Island added statutory language that provides immunity from criminal prosecution to “A licensed health care professional who administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death...”⁵⁸ While the intent of the policy as a whole is to encourage pain management, it reinforces an unfounded fear about opioids⁵⁹ that can itself contribute to inadequate treatment of pain. Such a provision is now present in 15 states.¹
- ◆ Adoption of Provisions Mandating Opioids as Treatment of Last Resort: Kentucky and Montana added provisions mandating that a physician always document that other treatment measures and drugs have been inadequate or not tolerated before beginning a regimen of controlled substances, suggesting that medical use of opioids is considered, as a matter of policy, a treatment of last resort (Criterion #9). Kentucky's new provision is as follows: “Before beginning a regimen of controlled drugs, the physician must determine, through actual clinical trial or through patient records and history that non-addictive medication regimens have been inadequate or are unacceptable for solid clinical reasons.”⁶⁰ Currently, 9 states have policies that consider opioids to be a treatment of last resort.^m
- ◆ Adoption of Intractable Pain Treatment Acts: Tennessee adopted an Intractable Pain Treatment Act (IPTA)⁶¹ containing a number of restrictive or ambiguous provisions, such as implying opioids are a treatment of last resort (Criterion #9) and their use is outside legitimate professional practice (Criterion #10), and confusing “addiction” with physical dependence or tolerance (Criterion #12). As of March 2003, 11 states have adopted IPTAs containing restrictive provisions.ⁿ

¹ These states are Iowa, Indiana, Kansas, Kentucky, Maryland, Michigan, Minnesota, New Hampshire, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, and Virginia.

^m These states are Arizona, Georgia, Kentucky, Louisiana, Mississippi, Montana, Ohio, Tennessee, Virginia, and West Virginia.

ⁿ These states are California, Colorado, Minnesota, Missouri, North Dakota, Oregon, Rhode Island, Tennessee, Texas, and West Virginia.



CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 2308

VERSION: AMENDED APRIL 19, 2006

AUTHOR: PLESCIA

**SPONSOR: CA AMBULATORY
ASSOCIATION**

RECOMMENDED POSITION:

SUBJECT: AMBULATORY SURGICAL CENTERS: LICENSURE

Existing Law:

- 1) Provides for the licensure and regulation of health facilities and clinics, including specialty clinics, by the State Department of Health Services (DHS). (H&S 1204)
- 2) Provides Medicare certification of ambulatory surgery centers. (42 CFR 416.2 (a))
- 3) Allows a surgical clinic that is licensed by the board to purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic. Clinics are required to keep records of the kind and amounts of drugs purchased, administered, and dispensed; records must be available and maintained for a minimum of seven years for inspection by all properly authorized personnel. (B&P 4190)

This Bill:

- 1) Deletes "surgical clinic" in B&P 4190 and replaces it with "ambulatory surgical center." (B&P 4190 Amended)
- 2) Defines an "ambulatory surgical center" as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. An ambulatory surgical center does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians or dentists may, at their option, apply for licensure. (H&S 1204 Amended)
- 3) Requires DHS to convene a workgroup, not later than January 15, 2007, to develop the licensure criteria to protect the health and safety of patients receiving care in an ambulatory surgical center, as defined in Section 1204. The workgroup is required to submit its conclusions and recommendations to the Assembly Committee on Health no later than April 15, 2007. The workgroup will include, but not be limited to, representatives from all of the following:
 - (1) State Department of Health Services.
 - (2) Office of Statewide Health Planning and Development.
 - (3) California Ambulatory Surgery Association.

- (4) California Medical Association.
- (5) California Orthopedic Association.
- (6) California Society of Anesthesiologists.
- (7) California Academy of Ophthalmology.

(H&S 1204.2)

Comment:

1) Author's Intent. Under current law not all ambulatory surgical centers (ASC) are licensed by the state, some are Medicare certified. The author's intent is to provide a consistent standard for licensing requirements of ASCs. Creating a state standard for will result in patients receiving a consistent level of care at ASCs.

2) Increased Volume in Licensure. DHS anticipates that once state standards are approved for licensing ASCs, there will be an increase in the number of applications for ASC licensing. Unfortunately, DHS does not know how many unlicensed ASC facilities there are in California so DHS cannot estimate the how many facilities will apply for a license once the new standards go into affect. The board anticipates that many of the newly licensed ASCs will apply for a clinic site license from the board; this will result in an increase workload for the board to process the clinic licenses.

3) Board Omnibus Bill. AB 2308 and the Board's Omnibus bill, SB 1476, would both amend a portion of B&P 4190. If both bills make it out of the legislature, chapter order of the bills will have to be decided.

4) History.

2006

- Apr. 19 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
- Apr. 18 In committee: Set, first hearing. Hearing canceled at the request of author.
- Apr. 6 Re-referred to Com. on HEALTH.
- Apr. 5 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
- Mar. 14 Referred to Com. on HEALTH.
- Feb. 23 From printer. May be heard in committee March 25.
- Feb. 22 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 19, 2006

AMENDED IN ASSEMBLY APRIL 5, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2308

Introduced by Assembly Member Plescia

February 22, 2006

An act to amend Sections 2472 and 4190 of the Business and Professions Code, to amend Sections 1204, 1206, 1214.1, 1226, 1226.5, 1233, 1242, and 1248.1 of, and to add Section 1204.2 to, the Health and Safety Code, and to amend Section 139.3 of the Labor Code, relating to health clinics.

LEGISLATIVE COUNSEL'S DIGEST

AB 2308, as amended, Plescia. Ambulatory surgical centers: licensure.

Existing law, with certain exceptions, provides for the licensure and regulation of health facilities and clinics, including specialty clinics, by the State Department of Health Services. Existing law defines a specialty clinic to include a surgical clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A violation of these provisions is a crime.

This bill would ~~delete the definition of a~~ *redesignate a* surgical clinic *as an ambulatory surgical clinic* for purposes of ~~various these~~ licensure and regulatory requirements, ~~would, instead, provide for the licensure of ambulatory surgical centers, as defined, and would make various conforming changes. The bill would require a licensed ambulatory surgical center to meet specified requirements. By~~

~~creating new crimes, this bill would impose a state-mandated local program.~~

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

This bill would also require the department, not later than January 15, 2007, to convene a workgroup of specified composition for the development of licensure criteria for ambulatory surgical care centers. This bill would require the workgroup to submit its findings and recommendations to the Legislature not later than April 15, 2007.

This bill would also permit the department to contract with outside personnel for the performance of inspections of ambulatory surgical centers, as necessary.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: ~~yes~~-no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 2472 of the Business and Professions
2 Code is amended to read:

3 2472. (a) The certificate to practice podiatric medicine
4 authorizes the holder to practice podiatric medicine.

5 (b) As used in this chapter, "podiatric medicine" means the
6 diagnosis, medical, surgical, mechanical, manipulative, and
7 electrical treatment of the human foot, including the ankle and
8 tendons that insert into the foot and the nonsurgical treatment of
9 the muscles and tendons of the leg governing the functions of the
10 foot.

11 (c) A doctor of podiatric medicine may not administer an
12 anesthetic other than local. If an anesthetic other than local is
13 required for any procedure, the anesthetic shall be administered
14 by another licensed health care practitioner who is authorized to
15 administer the required anesthetic within the scope of his or her
16 practice.

17 (d) (1) A doctor of podiatric medicine who is ankle certified
18 by the board on and after January 1, 1984, may do the following:

1 (A) Perform surgical treatment of the ankle and tendons at the
2 level of the ankle pursuant to subdivision (e).

3 (B) Perform services under the direct supervision of a
4 physician and surgeon, as an assistant at surgery, in surgical
5 procedures that are otherwise beyond the scope of practice of a
6 doctor of podiatric medicine.

7 (C) Perform a partial amputation of the foot no further
8 proximal than the Chopart's joint.

9 (2) Nothing in this subdivision shall be construed to permit a
10 doctor of podiatric medicine to function as a primary surgeon for
11 any procedure beyond his or her scope of practice.

12 (e) A doctor of podiatric medicine may perform surgical
13 treatment of the ankle and tendons at the level of the ankle only
14 in the following locations:

15 (1) A licensed general acute care hospital, as defined in
16 Section 1250 of the Health and Safety Code.

17 (2) A licensed ambulatory surgical center, as defined in
18 Section 1204 of the Health and Safety Code, if the doctor of
19 podiatric medicine has surgical privileges, including the privilege
20 to perform surgery on the ankle, in a general acute care hospital
21 described in paragraph (1) and meets all the protocols of the
22 ambulatory surgical center.

23 (3) An ambulatory surgical center that is certified to
24 participate in the Medicare Program under Title XVIII (42
25 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, if the
26 doctor of podiatric medicine has surgical privileges, including the
27 privilege to perform surgery on the ankle, in a general acute care
28 hospital described in paragraph (1) and meets all the protocols of
29 the surgical center.

30 (4) A freestanding physical plant housing outpatient services
31 of a licensed general acute care hospital, as defined in Section
32 1250 of the Health and Safety Code, if the doctor of podiatric
33 medicine has surgical privileges, including the privilege to
34 perform surgery on the ankle, in a general acute care hospital
35 described in paragraph (1). For purposes of this section, a
36 "freestanding physical plant" means any building that is not
37 physically attached to a building where inpatient services are
38 provided.

39 (5) An outpatient setting accredited pursuant to subdivision (g)
40 of Section 1248.1 of the Health and Safety Code.

1 (f) A doctor of podiatric medicine shall not perform an
2 admitting history and physical examination of a patient in an
3 acute care hospital where doing so would violate the regulations
4 governing the Medicare Program.

5 (g) A doctor of podiatric medicine licensed under this chapter
6 is a licentiate for purposes of paragraph (2) of subdivision (a) of
7 Section 805, and thus is a health care practitioner subject to the
8 provisions of Section 2290.5 pursuant to subdivision (b) of that
9 section.

10 SEC. 2. Section 4190 of the Business and Professions Code is
11 amended to read:

12 4190. (a) Notwithstanding any provision of this chapter, an
13 ambulatory surgical center, licensed pursuant to paragraph (1) of
14 subdivision (b) of Section 1204 of the Health and Safety Code,
15 accredited by an accreditation agency pursuant to Section 1248
16 of the Health and Safety Code, or certified to participate in the
17 Medicare Program under Title XVIII (42 U.S.C. Sec. 1395 et
18 seq.) of the federal Social Security Act, may purchase drugs at
19 wholesale for administration or dispensing, under the direction of
20 a physician, to patients registered for care at the center, as
21 provided in subdivision (b). The center shall keep records of the
22 kind and amounts of drugs purchased, administered, and
23 dispensed, and the records shall be available and maintained for
24 a minimum of seven years for inspection by all properly
25 authorized personnel.

26 (b) The drug distribution service of an ambulatory surgical
27 center shall be limited to the use of drugs for administration to
28 the patients of the ambulatory surgical center and to the
29 dispensing of drugs for the control of pain and nausea for patients
30 of the center. Drugs shall not be dispensed in an amount greater
31 than that required to meet the patient's needs for 72 hours. Drugs
32 for administration shall be those drugs directly applied, whether
33 by injection, inhalation, ingestion, or any other means, to the
34 body of a patient for his or her immediate needs.

35 (c) No ambulatory surgical center shall operate without a
36 license issued by the board nor shall it be entitled to the benefits
37 of this section until it has obtained a license from the board. Each
38 license shall be issued to a specific center and for a specific
39 location.

1 SEC. 3. Section 1204 of the Health and Safety Code is
2 amended to read:

3 1204. Clinics eligible for licensure pursuant to this chapter
4 are primary care clinics and specialty clinics.

5 (a) (1) Only the following defined classes of primary care
6 clinics shall be eligible for licensure:

7 (A) A "community clinic" means a clinic operated by a
8 tax-exempt nonprofit corporation that is supported and
9 maintained in whole or in part by donations, bequests, gifts,
10 grants, government funds or contributions, that may be in the
11 form of money, goods, or services. In a community clinic, any
12 charges to the patient shall be based on the patient's ability to
13 pay, utilizing a sliding fee scale. No corporation other than a
14 nonprofit corporation, exempt from federal income taxation
15 under paragraph (3) of subsection (c) of Section 501 of the
16 Internal Revenue Code of 1954 as amended, or a statutory
17 successor thereof, shall operate a community clinic; provided,
18 that the licensee of any community clinic so licensed on the
19 effective date of this section shall not be required to obtain
20 tax-exempt status under either federal or state law in order to be
21 eligible for, or as a condition of, renewal of its license. No
22 natural person or persons shall operate a community clinic.

23 (B) A "free clinic" means a clinic operated by a tax-exempt,
24 nonprofit corporation supported in whole or in part by voluntary
25 donations, bequests, gifts, grants, government funds or
26 contributions, that may be in the form of money, goods, or
27 services. In a free clinic there shall be no charges directly to the
28 patient for services rendered or for drugs, medicines, appliances,
29 or apparatuses furnished. No corporation other than a nonprofit
30 corporation exempt from federal income taxation under
31 paragraph (3) of subsection (c) of Section 501 of the Internal
32 Revenue Code of 1954 as amended, or a statutory successor
33 thereof, shall operate a free clinic; provided, that the licensee of
34 any free clinic so licensed on the effective date of this section
35 shall not be required to obtain tax-exempt status under either
36 federal or state law in order to be eligible for, or as a condition
37 of, renewal of its license. No natural person or persons shall
38 operate a free clinic.

39 (2) Nothing in this subdivision shall prohibit a community
40 clinic or a free clinic from providing services to patients whose

1 services are reimbursed by third-party payers, or from entering
2 into managed care contracts for services provided to private or
3 public health plan subscribers, as long as the clinic meets the
4 requirements identified in subparagraphs (A) and (B). For
5 purposes of this subdivision, any payments made to a community
6 clinic by a third-party payer, including, but not limited to, a
7 health care service plan, shall not constitute a charge to the
8 patient. This paragraph is a clarification of existing law.

9 (b) The following types of specialty clinics shall be eligible for
10 licensure as specialty clinics pursuant to this chapter:

11 ~~(1) An ambulatory surgical center means a clinic that is not~~
12 ~~part of a hospital and which, pursuant to Section 1204.2,~~
13 ~~primarily provides surgical services that do not exceed an~~
14 ~~average of four hours of total operating time to patients who do~~
15 ~~not require overnight hospitalization or who do not pose a~~
16 ~~significant safety risk according to classifications determined by~~
17 ~~the American Society of Anesthesiologists and, beginning at a~~
18 ~~time of postoperative care, remain less than 24 hours. An~~
19 ~~ambulatory surgical center does not include any place or~~
20 ~~establishment owned or leased and operated as a clinic or office~~
21 ~~by one or more physicians and surgeons, or dentists in individual~~
22 ~~or group practice, regardless of the name used publicly to~~
23 ~~identify the place or establishment, provided, however, that~~
24 ~~physicians and surgeons or dentists may, at their option, apply~~
25 ~~for licensure.~~

26 *(1) "Ambulatory surgical center" means a clinic that is not*
27 *part of a hospital and that provides ambulatory surgical care for*
28 *patients who remain less than 24 hours. An ambulatory surgical*
29 *center does not include any place or establishment owned or*
30 *leased and operated as a clinic or office by one or more*
31 *physicians or dentists in individual or group practice, regardless*
32 *of the name used publicly to identify the place or establishment,*
33 *provided, however, that physicians or dentists may, at their*
34 *option, apply for licensure.*

35 (2) A "chronic dialysis clinic" means a clinic that provides less
36 than 24-hour care for the treatment of patients with end-stage
37 renal disease, including renal dialysis services.

38 (3) A "rehabilitation clinic" means a clinic that, in addition to
39 providing medical services directly, also provides physical
40 rehabilitation services for patients who remain less than 24 hours.

1 Rehabilitation clinics shall provide at least two of the following
2 rehabilitation services: physical therapy, occupational therapy,
3 social, speech pathology, and audiology services. A rehabilitation
4 clinic does not include the offices of a private physician in
5 individual or group practice.

6 (4) An "alternative birth center" means a clinic that is not part
7 of a hospital and that provides comprehensive perinatal services
8 and delivery care to pregnant women who remain less than 24
9 hours at the facility.

10 SEC. 4. Section 1204.2 is added to the Health and Safety
11 Code, to read:

12 1204.2. (a) Notwithstanding Section 1248, ~~an ambulatory~~
13 ~~surgical center described in Section 1204 shall be subject to the~~
14 ~~requirements of this section. Nothing in this chapter shall~~
15 ~~prohibit an ambulatory surgical center from referring a~~
16 ~~nonemergency patient to a Tier 2 or lower classification facility~~
17 ~~as determined by the department. the department shall convene a~~
18 ~~workgroup, not later than January 15, 2007, to develop the~~
19 ~~licensure criteria to protect the health and safety of patients~~
20 ~~receiving care in an ambulatory surgical center, as defined in~~
21 ~~Section 1204. The workgroup shall submit its conclusions and~~
22 ~~recommendations to the Assembly Committee on Health no later~~
23 ~~than April 15, 2007. The workgroup shall include, but not be~~
24 ~~limited to, representatives from all of the following:~~

25 (1) State Department of Health Services.

26 (2) Office of Statewide Health Planning and Development.

27 (3) California Ambulatory Surgery Association.

28 (4) California Medical Association.

29 (5) California Orthopedic Association.

30 (6) California Society of Anesthesiologists.

31 (7) California Academy of Ophthalmology.

32 (b) The members of the workgroup shall not receive
33 compensation, but shall be individually reimbursed from private
34 sources for necessary travel expenses for the purposes of
35 attending meetings of the workgroup, including any public
36 meetings that the workgroup schedules.

37 (c) The department may contract for outside personnel to
38 perform inspections of ambulatory surgical centers, as
39 necessary. The department, when feasible, may contract with a
40 nonprofit, professional organization that has been approved as

1 *an accreditation agency, as defined in subdivision (d) of Section*
2 *1248, and has demonstrated the ability to administer the*
3 *provisions of this chapter.*

4 ~~(b) Failure to comply with this section may be grounds for~~
5 ~~denial, revocation, or suspension of the license by the~~
6 ~~department.~~

7 ~~(c) The department may accept accreditation by an~~
8 ~~accreditation agency, as defined in subdivision (d) of Section~~
9 ~~1248, as evidence that an ambulatory surgical center~~
10 ~~demonstrates compliance with, or meets the initial licensing~~
11 ~~requirements set forth in, this chapter.~~

12 ~~(d) The department may contract for outside personnel to~~
13 ~~perform inspections of ambulatory surgical centers as necessary.~~
14 ~~The department, when feasible, shall contract with a nonprofit,~~
15 ~~professional organizations that is approved as an accreditation~~
16 ~~agency, as defined in subdivision (d) of Section 1248, and has~~
17 ~~demonstrated the ability to administer the provisions of this~~
18 ~~chapter.~~

19 ~~(e) The department may make inspections and investigations~~
20 ~~as it deems necessary, to investigate complaints, follow up on~~
21 ~~adverse survey findings, or conduct periodic validation surveys.~~

22 ~~(f) An ambulatory surgical center that is licensed as a clinic~~
23 ~~pursuant to this section shall meet all of the following~~
24 ~~requirements:~~

25 ~~(1) The governing authority shall consist of one or more~~
26 ~~persons responsible for the organization and administration of the~~
27 ~~ambulatory surgical center. The governing authority shall do all~~
28 ~~of the following:~~

29 ~~(A) Adopt policies and procedures for the operation of the~~
30 ~~ambulatory surgical center to ensure compliance with state laws,~~
31 ~~regulations, and local ordinances.~~

32 ~~(B) Adopt the medical staff by laws.~~

33 ~~(C) Grant or deny clinical privileges of physicians and~~
34 ~~surgeons and other members of the medical staff and delineate, in~~
35 ~~writing, the clinical privileges of each medical staff member.~~

36 ~~(D) Adopt a quality management plan.~~

37 ~~(E) Appoint an administrator who shall have authority and~~
38 ~~responsibility to manage the center.~~

39 ~~(2) The administrator shall be responsible to the governing~~
40 ~~authority and act as a liaison between the governing authority;~~

1 ~~medical staff, and facility staff. In addition, the administrator~~
2 ~~shall be responsible for all of the following:~~

3 ~~(A) Developing and implementing written administrative~~
4 ~~policies and procedures governing all of the following:~~

5 ~~(i) Personnel employment, orientation, in-service, staffing, and~~
6 ~~recordkeeping.~~

7 ~~(ii) Patient admissions, rights and responsibilities, grievances,~~
8 ~~medical treatment, and recordkeeping.~~

9 ~~(iii) Advance directives, a term which means a living will,~~
10 ~~prehospital medical care directive, or health care power of~~
11 ~~attorney.~~

12 ~~(iv) Medications procurement and dispensing.~~

13 ~~(v) Contract services.~~

14 ~~(vi) Infection control, housekeeping, and maintenance.~~

15 ~~(vii) Quality management and recordkeeping.~~

16 ~~(viii) Emergency treatment and disaster plan.~~

17 ~~(ix) Equipment inspection.~~

18 ~~(B) Ensuring that all the policies and procedures are available~~
19 ~~to all employees in the facility.~~

20 ~~(C) Developing and implementing a quality management plan.~~
21 ~~The purpose of the quality management plan is to monitor and~~
22 ~~evaluate the provision of all aspects of patient care, including~~
23 ~~physicians and surgeons and contracted services. The quality~~
24 ~~management plan shall be in writing and describe the objectives,~~
25 ~~organization, scope, and process for improving quality of care,~~
26 ~~which shall include the monitoring activities.~~

27 ~~(D) Employing personnel to provide outpatient surgical~~
28 ~~services. "Outpatient surgical services" means those anesthesia~~
29 ~~and surgical services provided to a patient in an ambulatory~~
30 ~~surgical center that do not require planned inpatient care~~
31 ~~following a surgical procedure.~~

32 ~~(E) Ensuring that a pharmacy maintained by the center shall be~~
33 ~~registered as required by law.~~

34 ~~(F) Ensuring that pathology services are provided by a~~
35 ~~laboratory licensed, or exempt from licensure, as required by~~
36 ~~law.~~

37 ~~(G) Designating, in writing, an individual to be on duty, be in~~
38 ~~charge, and have access to all areas related to patient care and~~
39 ~~operation of the physical plant when the administrator is not~~
40 ~~present.~~

1 (H) ~~Posting a list of patient rights in a conspicuous area and~~
2 ~~making a reasonable effort to ensure that personnel apprise each~~
3 ~~patient or patient's representative of those rights and making a~~
4 ~~reasonable effort to ensure that language barriers or physical~~
5 ~~handicaps do not prevent each patient or patient's representative~~
6 ~~from becoming aware of those rights. "Patient's representative"~~
7 ~~means either a person acting on behalf of the patient with written~~
8 ~~consent of the patient or the patient's parent, legal guardian, or~~
9 ~~surrogate.~~

10 (I) ~~Ensuring that personnel are employed to meet the needs of~~
11 ~~patients and that job descriptions that define qualifications,~~
12 ~~duties, and responsibilities are established for all personnel.~~

13 (J) ~~Requiring personnel, prior to being employed and annually~~
14 ~~thereafter, to submit either one of the following as evidence of~~
15 ~~freedom from pulmonary tuberculosis:~~

16 (i) ~~A report of a negative Mantoux skin test taken within six~~
17 ~~months of submitting the report.~~

18 (ii) ~~A written statement from a physician stating that, upon an~~
19 ~~evaluation of a positive Mantoux skin test taken within six~~
20 ~~months of submitting the physician's statement or a history of a~~
21 ~~positive Mantoux skin test, the individual was found to be free~~
22 ~~from tuberculosis.~~

23 (K) ~~Providing orientation to each employee within the first~~
24 ~~week of employment. Orientation shall be specific to the position~~
25 ~~held by the employee.~~

26 (L) ~~Employing a registered nurse as the director of nursing~~
27 ~~who shall be responsible for the management and supervision of~~
28 ~~nursing services, including all of the following:~~

29 (i) ~~Developing and implementing written nursing and patient~~
30 ~~care policies and procedures, including medications~~
31 ~~administration, storage, and disposal.~~

32 (ii) ~~Ensuring that the facility is staffed based on the number of~~
33 ~~patients and their health care needs.~~

34 (iii) ~~Participating in quality management activities.~~

35 (iv) ~~Appointing a registered nurse, in writing, to act in the~~
36 ~~absence of the director of nursing.~~

37 (M) ~~Maintaining a record of quality management activities and~~
38 ~~ensuring that any conclusions and recommendations on findings~~
39 ~~of quality management activities are reported to the governing~~
40 ~~authority.~~

1 ~~(N) Ensuring there is a current listing of all surgical~~
2 ~~procedures offered by the center and maintaining a chronological~~
3 ~~register of all surgical procedures performed.~~

4 ~~(O) Ensuring that a roster of medical staff that have surgical or~~
5 ~~anesthesia privileges at the center is available to the center staff,~~
6 ~~specifying the privileges and limitations of each person on the~~
7 ~~roster.~~

8 ~~(P) Ensuring that a medical record is established and~~
9 ~~maintained for each patient. Medical and facility staff shall sign~~
10 ~~with surnames and date their entries in a patient's medical record.~~
11 ~~Staff shall release medical record information only after~~
12 ~~receiving the patient's or patient representative's written consent,~~
13 ~~or as otherwise required or permitted by law. The medical record~~
14 ~~shall contain all of the following:~~

- 15 ~~(i) Name and address of patient and patient's representative.~~
- 16 ~~(ii) Documentation of advance directives.~~
- 17 ~~(iii) Admitting diagnosis.~~
- 18 ~~(iv) Medical history and physical examination.~~
- 19 ~~(v) Laboratory and radiology reports.~~
- 20 ~~(vi) Consent forms.~~
- 21 ~~(vii) Physician orders and notations.~~
- 22 ~~(viii) Surgeon's operative report.~~
- 23 ~~(ix) Anesthesia report.~~
- 24 ~~(x) Nursing care notations.~~
- 25 ~~(xi) Medications and treatments administered.~~
- 26 ~~(xii) Written acknowledgment of receipt of discharge~~
27 ~~instructions by the patient or patient's representative.~~

28 ~~(Q) Ensuring that the medical record of discharged patient is~~
29 ~~completed within 30 days of the discharge.~~

30 ~~(R) Ensuring that the medical records are maintained for a~~
31 ~~period of seven years. Medical records shall be retained onsite at~~
32 ~~the center, or retrievable by center staff within two hours of a~~
33 ~~request, for a period of one year from a patient's discharge.~~

34 ~~(S) Ensuring that written infection control policies and~~
35 ~~procedures are established and implemented for the surveillance,~~
36 ~~control, and prevention of infection. The policies and procedures~~
37 ~~shall include all of the following:~~

- 38 ~~(i) Sterilization methods.~~
- 39 ~~(ii) Storage, maintenance, and distribution of sterile supplies~~
40 ~~and equipment.~~

1 (iii) Disposal of waste, including blood, body tissue, and fluid.

2 (T) Ensuring that housekeeping and maintenance services are
3 provided to maintain a safe and sanitary environment.

4 (U) Ensuring that equipment is operational, inspected, and
5 maintained in accordance with the center's policies and
6 procedures. These policies and procedures shall address all of the
7 following:

8 (i) Testing, calibrating, servicing, or repairing of equipment to
9 ensure that the equipment is free from fire and electrical hazards.

10 (ii) Maintaining records documenting service and calibration
11 information.

12 (iii) The use, maintenance, and storage of oxygen and other
13 flammable gases in accordance with applicable law.

14 (iv) The use and maintenance of electrical equipment in
15 accordance with applicable law.

16 (V) Ensuring that employees who provide direct patient care
17 shall:

18 (i) Be 18 years of age or older.

19 (ii) Be certified in cardiopulmonary resuscitation within the
20 first month of employment, and maintain current certification
21 thereafter.

22 (iii) Attend six hours of in-service education per year, which is
23 exclusive of orientation, and cardiopulmonary resuscitation and
24 which relates to the purposes and function of an ambulatory
25 surgical center.

26 (W) Ensuring that personnel records are maintained, including
27 the application for employment, verification of training,
28 certification, or licensure, initial proof of freedom from
29 tuberculosis and annual verification statement thereafter, and
30 orientation and in-service training records.

31 (X) Ensuring the development of a written disaster plan of
32 operation with procedures to be followed in the event of a fire or
33 threat to patient safety and shall ensure that an emergency
34 evacuation route is posted in every room where patients may be
35 present, except restrooms.

36 (Y) Ensuring all of the following with respect to emergency
37 preparation:

38 (i) Fire drills are conducted every three months, and all staff
39 members on duty participate.

1 (ii) Records of the drills include the date, time, and critique of
2 the drills.

3 (iii) Records of the drills are maintained for one year.

4 (3) A registered nurse shall function as a circulating nurse
5 during each surgical procedure. A registered nurse shall be
6 present in the recovery room whenever patients are in the
7 recovery room. A registered nurse shall be in the facility until all
8 patients are discharged. A registered nurse shall ensure that the
9 patient or patient's representative acknowledges, in writing, the
10 physician's written discharge instructions.

11 (4) The individual responsible for performing the operative
12 procedure shall complete an operative report and any necessary
13 discharge instructions according to medical staff bylaws and
14 ambulatory surgical center policies and procedures. The
15 individual responsible for the administration of anesthesia shall
16 complete an anesthesia report and any necessary discharge
17 instructions according to medical staff bylaws and center policies
18 and procedures.

19 (5) A licensed physician and surgeon or licensed health care
20 professional shall remain on the premises until all patients are
21 discharged from the recovery room pursuant to subdivision (b) of
22 Section 1248.15.

23 (6) If an ambulatory surgical center ceases operation, the
24 governing authority shall ensure the preservation of records and
25 notify the department, in writing, of the location of the records.

26 (7) The medical staff shall have responsibility for all of the
27 following:

28 (A) Approval of bylaws for the conduct of medical staff
29 activities.

30 (B) Conducting medical peer review and submitting
31 recommendations to the governing authority for approval.

32 (C) Establishing written policies and procedures that define
33 the extent of emergency treatment to be performed in the center,
34 including cardiopulmonary resuscitation procedures and
35 provisions for the emergency transfer of a patient.

36 (8) A medical staff physician shall admit patients to the
37 facility who do not require overnight hospitalization or who do
38 not pose a significant safety risk according to classifications
39 determined by the American Society of Anesthesiologists and,
40 beginning at a time of postoperative care, remain less than 24

1 hours and who do not, on average, require more than four hours
2 of total operating time.

3 (9) Within 30 days prior to admission, a medical staff member
4 shall complete a medical history and physical examination of the
5 patient. The individual responsible for performing the operative
6 procedure shall document the preoperative diagnosis and the
7 procedure to be performed. The nursing staff shall ensure that all
8 of the following documents are in the patient's medical record
9 prior to surgery:

10 (A) A medical history and results of a current physical
11 examination.

12 (B) A preoperative diagnosis and the results of any laboratory
13 tests or procedures relative to the surgery and the condition of the
14 patient.

15 (C) Validation of informed consent by the patient or patient's
16 representative for the surgical procedure and care of the patient.

17 (D) Physicians orders.

18 (10) Staff shall provide emergency treatment according to the
19 center's policies and procedures.

20 (11) The ambulatory surgical center shall pass an initial
21 inspection for fire safety by the fire authority having jurisdiction.

22 (12) The ambulatory surgical center shall ensure that there
23 shall be two recovery beds for each operating room, for up to
24 four operating rooms, whenever general anesthesia is
25 administered. One additional recovery bed shall be required for
26 each additional operating room.

27 (13) Recovery beds or gurneys shall be located in a space that
28 provides for a minimum of 70 square feet per bed, allowing three
29 feet or more between beds and between the sides of a bed and the
30 wall.

31 (14) The ambulatory surgical center may provide recliner
32 chairs in the recovery room area for patients who have not
33 received general anesthesia.

34 (15) The surgical center shall ensure that the following shall
35 be available in the surgical suite:

36 (A) Oxygen and the means of administration.

37 (B) Mechanical ventilatory assistance equipment, including
38 airways.

39 (C) Manual breathing bag, and suction apparatus.

1 ~~(D) Cardiac monitor, defibrillator, and cardiopulmonary~~
2 ~~resuscitation drugs as determined by the facility's policies and~~
3 ~~procedures.~~

4 ~~(E) Noninvasive blood pressure monitor.~~

5 ~~(F) Oxygen saturation monitor.~~

6 ~~(G) Temperature monitor and an end-tidal CO₂ when general~~
7 ~~anesthesia is administered.~~

8 SEC. 5. Section 1206 of the Health and Safety Code is
9 amended to read:

10 1206. This chapter does not apply to the following:

11 (a) Except with respect to the option provided with regard to
12 ambulatory surgical ~~clinics~~ *centers* described in paragraph (1) of
13 subdivision (b) of Section 1204 and further, with respect to
14 chronic dialysis clinics described in paragraph (2) of subdivision
15 (b) of Section 1204, any place or establishment owned or leased
16 and operated as a clinic or office by one or more licensed health
17 care practitioners and used as an office for the practice of their
18 profession, within the scope of their license, regardless of the
19 name used publicly to identify the place or establishment.

20 (b) Any clinic directly conducted, maintained, or operated by
21 the United States or by any of its departments, officers, or
22 agencies, and any primary care clinic specified in subdivision (a)
23 of Section 1204 that is directly conducted, maintained, or
24 operated by this state or by any of its political subdivisions or
25 districts, or by any city. Nothing in this subdivision precludes the
26 state department from adopting regulations that utilize clinic
27 licensing standards as eligibility criteria for participation in
28 programs funded wholly or partially under Title XVIII or XIX of
29 the federal Social Security Act.

30 (c) Any clinic conducted, maintained, or operated by a
31 federally recognized Indian tribe or tribal organization, as
32 defined in Section 450 or 1601 of Title 25 of the United States
33 Code, that is located on land recognized as tribal land by the
34 federal government.

35 (d) Clinics conducted, operated, or maintained as outpatient
36 departments of hospitals.

37 (e) Any facility licensed as a health facility under Chapter 2
38 (commencing with Section 1250).

1 (f) Any freestanding clinical or pathological laboratory
2 licensed under Chapter 3 (commencing with Section 1200) of
3 Division 2 of the Business and Professions Code.

4 (g) A clinic operated by, or affiliated with, any institution of
5 learning that teaches a recognized healing art and is approved by
6 the state board or commission vested with responsibility for
7 regulation of the practice of that healing art.

8 (h) A clinic that is operated by a primary care community or
9 free clinic and that is operated on separate premises from the
10 licensed clinic and is only open for limited services of no more
11 than 20 hours a week. An intermittent clinic as described in this
12 subdivision shall, however, meet all other requirements of law,
13 including administrative regulations and requirements, pertaining
14 to fire and life safety.

15 (i) The offices of physicians in group practice who provide a
16 preponderance of their services to members of a comprehensive
17 group practice prepayment health care service plan subject to
18 Chapter 2.2 (commencing with Section 1340).

19 (j) Student health centers operated by public institutions of
20 higher education.

21 (k) Nonprofit speech and hearing centers, as defined in Section
22 1201.5. Any nonprofit speech and hearing clinic desiring an
23 exemption under this subdivision shall make application therefor
24 to the director, who shall grant the exemption to any facility
25 meeting the criteria of Section 1201.5. Notwithstanding the
26 licensure exemption contained in this subdivision, a nonprofit
27 speech and hearing center shall be deemed to be an organized
28 outpatient clinic for purposes of qualifying for reimbursement as
29 a rehabilitation center under the Medi-Cal Act (Chapter 7
30 (commencing with Section 14000) of Part 3 of Division 9 of the
31 Welfare and Institutions Code).

32 (l) A clinic operated by a nonprofit corporation exempt from
33 federal income taxation under paragraph (3) of subsection (c) of
34 Section 501 of the Internal Revenue Code of 1954, as amended,
35 or a statutory successor thereof, that conducts medical research
36 and health education and provides health care to its patients
37 through a group of 40 or more physicians and surgeons, who are
38 independent contractors representing not less than 10
39 board-certified specialties, and not less than two-thirds of whom
40 practice on a full-time basis at the clinic.

1 (m) Any clinic, limited to in vivo diagnostic services by
2 magnetic resonance imaging functions or radiological services
3 under the direct and immediate supervision of a physician and
4 surgeon who is licensed to practice in California. This shall not
5 be construed to permit cardiac catheterization or any treatment
6 modality in these clinics.

7 (n) A clinic operated by an employer or jointly by two or more
8 employers for their employees only, or by a group of employees,
9 or jointly by employees and employers, without profit to the
10 operators thereof or to any other person, for the prevention and
11 treatment of accidental injuries to, and the care of the health of,
12 the employees comprising the group.

13 (o) A community mental health center, as defined in Section
14 5601.5 of the Welfare and Institutions Code.

15 (p) (1) A clinic operated by a nonprofit corporation exempt
16 from federal income taxation under paragraph (3) of subsection
17 (c) of Section 501 of the Internal Revenue Code of 1954, as
18 amended, or a statutory successor thereof, as an entity organized
19 and operated exclusively for scientific and charitable purposes
20 and that satisfied all of the following requirements on or before
21 January 1, 2005:

22 (A) Commenced conducting medical research on or before
23 January 1, 1982, and continues to conduct medical research.

24 (B) Conducted research in, among other areas, prostatic
25 cancer, cardiovascular disease, electronic neural prosthetic
26 devices, biological effects and medical uses of lasers, and human
27 magnetic resonance imaging and spectroscopy.

28 (C) Sponsored publication of at least 200 medical research
29 articles in peer-reviewed publications.

30 (D) Received grants and contracts from the National Institutes
31 of Health.

32 (E) Held and licensed patents on medical technology.

33 (F) Received charitable contributions and bequests totaling at
34 least five million dollars (\$5,000,000).

35 (G) Provides health care services to patients only:

36 (i) In conjunction with research being conducted on
37 procedures or applications not approved or only partially
38 approved for payment (I) under the Medicare Program pursuant
39 to Section 1359y(a)(1)(A) of Title 42 of the United States Code,
40 or (II) by a health care service plan registered under Chapter 2.2

1 (commencing with Section 1340), or a disability insurer
2 regulated under Chapter 1 (commencing with Section 10110) of
3 Part 2 of Division 2 of the Insurance Code; provided that services
4 may be provided by the clinic for an additional period of up to
5 three years following the approvals, but only to the extent
6 necessary to maintain clinical expertise in the procedure or
7 application for purposes of actively providing training in the
8 procedure or application for physicians and surgeons unrelated to
9 the clinic.

10 (ii) Through physicians and surgeons who, in the aggregate,
11 devote no more than 30 percent of their professional time for the
12 entity operating the clinic, on an annual basis, to direct patient
13 care activities for which charges for professional services are
14 paid.

15 (H) Makes available to the public the general results of its
16 research activities on at least an annual basis, subject to good
17 faith protection of proprietary rights in its intellectual property.

18 (I) Is a freestanding clinic, whose operations under this
19 subdivision are not conducted in conjunction with any affiliated
20 or associated health clinic or facility defined under this division,
21 except a clinic exempt from licensure under subdivision (m). For
22 purposes of this subparagraph, a freestanding clinic is defined as
23 “affiliated” only if it directly, or indirectly through one or more
24 intermediaries, controls, or is controlled by, or is under common
25 control with, a clinic or health facility defined under this
26 division, except a clinic exempt from licensure under subdivision
27 (m). For purposes of this subparagraph, a freestanding clinic is
28 defined as “associated” only if more than 20 percent of the
29 directors or trustees of the clinic are also the directors or trustees
30 of any individual clinic or health facility defined under this
31 division, except a clinic exempt from licensure under subdivision
32 (m). Any activity by a clinic under this subdivision in connection
33 with an affiliated or associated entity shall fully comply with the
34 requirements of this subdivision. This subparagraph shall not
35 apply to agreements between a clinic and any entity for purposes
36 of coordinating medical research.

37 (2) By January 1, 2007, and every five years thereafter, the
38 Legislature shall receive a report from each clinic meeting the
39 criteria of this subdivision and any other interested party
40 concerning the operation of the clinic’s activities. The report

1 shall include, but not be limited to, an evaluation of how the
2 clinic impacted competition in the relevant health care market,
3 and a detailed description of the clinic's research results and the
4 level of acceptance by the payer community of the procedures
5 performed at the clinic. The report shall also include a
6 description of procedures performed both in clinics governed by
7 this subdivision and those performed in other settings. The cost
8 of preparing the reports shall be borne by the clinics that are
9 required to submit them to the Legislature pursuant to this
10 paragraph.

11 SEC. 6. Section 1214.1 of the Health and Safety Code is
12 amended to read:

13 1214.1. Notwithstanding Section 1214, each application for
14 an ambulatory surgical-~~clinic~~ center or a chronic dialysis clinic
15 under this chapter for an initial license, renewal license, license
16 upon change of ownership, or special permit shall be
17 accompanied by an annual fee of three hundred dollars (\$300)
18 plus an amount equal to 0.0003 times the clinic's operating cost
19 for the last completed fiscal year.

20 SEC. 7. Section 1226 of the Health and Safety Code is
21 amended to read:

22 1226. (a) The regulations shall prescribe the kinds of services
23 which may be provided by clinics in each category of licensure
24 and shall prescribe minimum standards of adequacy, safety, and
25 sanitation of the physical plant and equipment, minimum
26 standards for staffing with duly qualified personnel, and
27 minimum standards for providing the services offered. These
28 minimum standards shall be based on the type of facility, the
29 needs of the patients served, and the types and levels of services
30 provided.

31 (b) The Office of Statewide Health Planning and
32 Development, in consultation with the Community Clinics
33 Advisory Committee, shall prescribe minimum construction
34 standards of adequacy and safety for the physical plant of clinics
35 as found in the California Building Standards Code.

36 (c) A city or county, as applicable, shall have plan review and
37 building inspection responsibilities for the construction or
38 alteration of buildings described in paragraph (1) and paragraph
39 (2) of subdivision (b) of Section 1204 and shall apply the
40 provisions of the latest edition of the California Building

1 Standards Code in conducting these plan review responsibilities.
2 For these buildings, construction and alteration shall include
3 conversion of a building to a purpose specified in paragraphs (1)
4 and (2) of subdivision (b) of Section 1204.

5 Upon the initial submittal to a city or county by the governing
6 authority or owner of these clinics for plan review and building
7 inspection services, the city or county shall reply in writing to the
8 clinic whether or not the plan review by the city or county will
9 include a certification as to whether or not the clinic project
10 submitted for plan review meets the standards as propounded by
11 the office in the California Building Standards Code.

12 If the city or county indicates that its review will include this
13 certification it shall do all of the following:

14 (1) Apply the applicable clinic provisions of the latest edition
15 of the California Building Standards Code.

16 (2) Certify in writing, to the applicant within 30 days of
17 completion of construction whether or not these standards have
18 been met.

19 (d) If upon initial submittal, the city or county indicates that its
20 plan review will not include this certification, the governing
21 authority or owner of the clinic shall submit the plans to the
22 Office of Statewide Health Planning and Development who shall
23 review the plans for certification whether or not the clinic project
24 meets the standards, as propounded by the office in California
25 Building Standards Code.

26 (e) When the office performs review for certification, the
27 office shall charge a fee in an amount that does not exceed its
28 actual costs.

29 (f) The office of the State Fire Marshal shall prescribe
30 minimum safety standards for fire and life safety in ambulatory
31 surgical centers.

32 (g) Notwithstanding subdivision (c), the governing authority
33 or owner of a clinic may request the office to perform plan
34 review services for buildings described in subdivision (c). If the
35 office agrees to perform these services, after consultation with
36 the local building official, the office shall charge an amount not
37 to exceed its actual costs. The construction or alteration of these
38 buildings shall conform to the applicable provisions of the latest
39 edition of the California Building Standards Code for purposes of
40 the plan review by the office pursuant to this subdivision.

1 (h) Regulations adopted pursuant to this chapter establishing
2 standards for laboratory services shall not be applicable to any
3 clinic that operates a clinical laboratory licensed pursuant to
4 Section 1265 of the Business and Professions Code.

5 SEC. 8. Section 1226.5 of the Health and Safety Code is
6 amended to read:

7 1226.5. (a) It is the intent of the Legislature to establish
8 seismic safety standards for facilities licensed as ambulatory
9 surgical centers pursuant to this chapter, and for facilities
10 certified for participation in the federal Medicare Program as
11 ambulatory surgical centers, which accommodate surgical
12 patients under general anesthesia, but are not required to remain
13 open and usable after an earthquake to accommodate emergency
14 patients.

15 (b) A facility described in subdivision (a) which, after January
16 1, 1991, anchors fixed medical equipment to the floor or roof of
17 the facility with a gross operating weight of more than 400
18 pounds or anchors fixed medical equipment to the walls or
19 ceiling with a gross operating weight of more than 20 pounds
20 shall retain the services of an architect licensed in California, a
21 structural engineer licensed in California, or a civil engineer
22 registered in California to assure that the equipment is anchored
23 in such a manner to meet the requirements of an occupancy
24 importance factor of 1.00, as set forth in Title 24 of the
25 California Code of Regulations.

26 (c) A facility described in subdivision (a) which retains the
27 services of an architect or engineer for the anchorage of fixed
28 medical equipment shall keep available for inspection by the
29 department for a period of five years following the installation, a
30 current written certification from the architect or engineer that
31 the equipment is mounted in accordance with the applicable
32 requirements.

33 SEC. 9. Section 1233 of the Health and Safety Code is
34 amended to read:

35 1233. An ambulatory surgical center may restrict use of its
36 facilities to members of the medical staff of the ambulatory
37 surgical center and other physicians and surgeons approved by
38 the medical staff to practice at the center.

39 SEC. 10. Section 1242 of the Health and Safety Code is
40 amended to read:

1 1242. The director may temporarily suspend any license
2 issued to a specialty clinic or special permit prior to any hearing,
3 when in his opinion such action is necessary to protect the public
4 welfare. The director shall notify the licensee or holder of a
5 special permit of the temporary suspension and the effective date
6 thereof, and at the same time shall serve such provider with an
7 accusation. Upon receipt of a notice of defense by the licensee or
8 holder of a special permit, the director shall set the matter for
9 hearing within 30 days after receipt of such notice. The
10 temporary suspension shall remain in effect until the time when
11 the hearing is completed and the director has made a final
12 determination on the merits; provided, however, that the
13 temporary suspension shall be deemed vacated if the director
14 fails to make a final determination on the merits within 60 days
15 after the original hearing has been completed.

16 If the provisions of this chapter or the rules or regulations
17 promulgated by the director are violated by a licensed
18 ambulatory surgical center or chronic dialysis clinic or holder of
19 a special permit which is a group, corporation, or other
20 association, the director may suspend the license or special
21 permit of the organization or may suspend the license or special
22 permit as to any individual person within the organization who is
23 responsible for the violation.

24 SEC. 11. Section 1248.1 of the Health and Safety Code is
25 amended to read:

26 1248.1. No association, corporation, firm, partnership, or
27 person shall operate, manage, conduct, or maintain an outpatient
28 setting in this state, unless the setting is one of the following:

29 (a) An ambulatory surgical center that is certified to
30 participate in the Medicare Program under Title XVIII (42
31 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act.

32 (b) Any clinic conducted, maintained, or operated by a
33 federally recognized Indian tribe or tribal organization, as
34 defined in Section 450 or 1601 of Title 25 of the United States
35 Code, and located on land recognized as tribal land by the federal
36 government.

37 (c) Any clinic directly conducted, maintained, or operated by
38 the United States or by any of its departments, officers, or
39 agencies.

1 (d) Any primary care clinic licensed under subdivision (a) of
2 Section 1204 or any ambulatory surgical center licensed under
3 subdivision (b) of Section 1204.

4 (e) Any health facility licensed as a general acute care hospital
5 under Chapter 2 (commencing with Section 1250).

6 (f) Any outpatient setting to the extent that it is used by a
7 dentist or physician and surgeon in compliance with Article 2.7
8 (commencing with Section 1646) or Article 2.8 (commencing
9 with Section 1647) of Chapter 4 of Division 2 of the Business
10 and Professions Code.

11 (g) An outpatient setting accredited by an accreditation agency
12 approved by the division pursuant to this chapter.

13 (h) A setting, including, but not limited to, a mobile van, in
14 which equipment is used to treat patients admitted to a facility
15 described in subdivision (a), (d), or (e), and in which the
16 procedures performed are staffed by the medical staff of, or other
17 health care practitioners with clinical privileges at, the facility
18 and are subject to the peer review process of the facility but
19 which setting is not a part of a facility described in subdivision
20 (a), (d), or (e).

21 Nothing in this section shall relieve an association, corporation,
22 firm, partnership, or person from complying with all other
23 provisions of law that are otherwise applicable.

24 SEC. 12. Section 139.3 of the Labor Code is amended to
25 read:

26 139.3. (a) Notwithstanding any other provision of law, to the
27 extent those services are paid pursuant to Division 4
28 (commencing with Section 3200), it is unlawful for a physician
29 to refer a person for clinical laboratory, diagnostic nuclear
30 medicine, radiation oncology, physical therapy, physical
31 rehabilitation, psychometric testing, home infusion therapy,
32 outpatient surgery, or diagnostic imaging goods or services
33 whether for treatment or medical-legal purposes if the physician
34 or his or her immediate family, has a financial interest with the
35 person or in the entity that receives the referral.

36 (b) For purposes of this section and Section 139.31, the
37 following shall apply:

38 (1) "Diagnostic imaging" includes, but is not limited to, all
39 X-ray, computed axial tomography magnetic resonance imaging,

1 nuclear medicine, positron emission tomography,
2 mammography, and ultrasound goods and services.

3 (2) "Immediate family" includes the spouse and children of
4 the physician, the parents of the physician, and the spouses of the
5 children of the physician.

6 (3) "Physician" means a physician as defined in Section
7 3209.3.

8 (4) A "financial interest" includes, but is not limited to, any
9 type of ownership, interest, debt, loan, lease, compensation,
10 remuneration, discount, rebate, refund, dividend, distribution,
11 subsidy, or other form of direct or indirect payment, whether in
12 money or otherwise, between a licensee and a person or entity to
13 whom the physician refers a person for a good or service
14 specified in subdivision (a). A financial interest also exists if
15 there is an indirect relationship between a physician and the
16 referral recipient, including, but not limited to, an arrangement
17 whereby a physician has an ownership interest in any entity that
18 leases property to the referral recipient. Any financial interest
19 transferred by a physician to, or otherwise established in, any
20 person or entity for the purpose of avoiding the prohibition of
21 this section shall be deemed a financial interest of the physician.

22 (5) A "physician's office" is either of the following:

23 (A) An office of a physician in solo practice.

24 (B) An office in which the services or goods are personally
25 provided by the physician or by employees in that office, or
26 personally by independent contractors in that office, in
27 accordance with other provisions of law. Employees and
28 independent contractors shall be licensed or certified when that
29 licensure or certification is required by law.

30 (6) The "office of a group practice" is an office or offices in
31 which two or more physicians are legally organized as a
32 partnership, professional corporation, or not-for-profit
33 corporation licensed according to subdivision (a) of Section 1204
34 of the Health and Safety Code for which all of the following are
35 applicable:

36 (A) Each physician who is a member of the group provides
37 substantially the full range of services that the physician
38 routinely provides, including medical care, consultation,
39 diagnosis, or treatment, through the joint use of shared office
40 space, facilities, equipment, and personnel.

1 (B) Substantially all of the services of the physicians who are
2 members of the group are provided through the group and are
3 billed in the name of the group and amounts so received are
4 treated as receipts of the group, and except that in the case of
5 multispecialty clinics, as defined in subdivision (I) of Section
6 1206 of the Health and Safety Code, physician services are billed
7 in the name of the multispecialty clinic and amounts so received
8 are treated as receipts of the multispecialty clinic.

9 (C) The overhead expenses of, and the income from, the
10 practice are distributed in accordance with methods previously
11 determined by members of the group.

12 (7) Outpatient surgery includes both of the following:

13 (A) Any procedure performed on an outpatient basis in the
14 operating rooms, ambulatory surgery rooms, endoscopy units,
15 cardiac catheterization laboratories, or other sections of a
16 freestanding ambulatory surgical center, whether or not licensed
17 under paragraph (1) of subdivision (b) of Section 1204 of the
18 Health and Safety Code.

19 (B) The ambulatory surgery itself.

20 (c) (1) It is unlawful for a licensee to enter into an
21 arrangement or scheme, such as a cross-referral arrangement, that
22 the licensee knows, or should know, has a principal purpose of
23 ensuring referrals by the licensee to a particular entity that, if the
24 licensee directly made referrals to that entity, would be in
25 violation of this section.

26 (2) It shall be unlawful for a physician to offer, deliver,
27 receive, or accept any rebate, refund, commission, preference,
28 patronage dividend, discount, or other consideration, whether in
29 the form of money or otherwise, as compensation or inducement
30 for a referred evaluation or consultation.

31 (d) No claim for payment shall be presented by an entity to
32 any individual, third-party payer, or other entity for any goods or
33 services furnished pursuant to a referral prohibited under this
34 section.

35 (e) A physician who refers to or seeks consultation from an
36 organization in which the physician has a financial interest shall
37 disclose this interest to the patient or if the patient is a minor, to
38 the patient's parents or legal guardian in writing at the time of the
39 referral.

1 (f) No insurer, self-insurer, or other payer shall pay a charge or
2 lien for any goods or services resulting from a referral in
3 violation of this section.

4 (g) A violation of subdivision (a) shall be a misdemeanor. The
5 appropriate licensing board shall review the facts and
6 circumstances of any conviction pursuant to subdivision (a) and
7 take appropriate disciplinary action if the licensee has committed
8 unprofessional conduct. Violations of this section may also be
9 subject to civil penalties of up to five thousand dollars (\$5,000)
10 for each offense, which may be enforced by the Insurance
11 Commissioner, Attorney General, or a district attorney. A
12 violation of subdivision (c), (d), (e), or (f) is a public offense and
13 is punishable upon conviction by a fine not exceeding fifteen
14 thousand dollars (\$15,000) for each violation and appropriate
15 disciplinary action, including revocation of professional
16 licensure, by the Medical Board of California or other
17 appropriate governmental agency.

18 ~~SEC. 13. No reimbursement is required by this act pursuant~~
19 ~~to Section 6 of Article XIII B of the California Constitution~~
20 ~~because the only costs that may be incurred by a local agency or~~
21 ~~school district will be incurred because this act creates a new~~
22 ~~crime or infraction, eliminates a crime or infraction, or changes~~
23 ~~the penalty for a crime or infraction, within the meaning of~~
24 ~~Section 17556 of the Government Code, or changes the~~
25 ~~definition of a crime within the meaning of Section 6 of Article~~
26 ~~XIII B of the California Constitution.~~



CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 2583

VERSION: AMENDED MARCH 27, 2006

AUTHOR: NATION

SPONSOR: AUTHOR

RECOMMENDED POSITION: OPPOSE UNLESS AMENDED

SUBJECT: DISPENSING PRESCRIPTION DRUGS AND DEVICES: REFUSAL TO DISPENSE

Existing Law:

1) States that no licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary action by his or her licensing agency. (B&P 733)

2) Requires a licentiate to dispense drugs and devices pursuant to a lawful order or prescription unless one of the following circumstances exists: 1) dispensing pursuant the prescription is contrary to law or the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; 2) the prescription drug or device is not in stock; or 3) the licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription, and the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects; and the employer can, provide a reasonable accommodation of the licentiate's objection by establishing protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. (B&P 733)

Requires every pharmacy to prominently a place conspicuous to and readable by prescription drug consumers a notice provided by the board concerning the availability of prescription price information, the possibility of generic drug product selection, and the type of services provided by pharmacies; alternatively, a written receipt that contains the required information on the notice may be provided to consumers to posting the notice in the pharmacy. (B&P 4122)

Specifies the wording of the Notice to Consumers that must be posted in accordance with B&P section 4122. (CCR 1707.2)

This Bill:

1) Requires the board create and provide to licentiates or licentiate's employers a sign informing patients of the following:

- i. If a licentiate refuses to dispense a prescription drug or device based on ethical, moral, or religious grounds, the patient has a right to timely access to the prescribed drug or device.
- ii. How a patient may file a complaint with the board, including contact information for the board. (B&P 733 Amended)

3) Requires the licentiate or licentiate's employer to place the sign in a location that is visible to patients and that is at or near the entrance of the business if a licentiate, pursuant to B&P 733, declines to dispense a prescription drug or device. (B&P 733 Amended)

Comment:

1) Author's Intent. The author's intent is to "ensure patients receive their prescription drugs in a timely manner, especially when a pharmacist chooses not to fill the prescription based on ethical, moral or religious reasons. A sign notifying a patient that a pharmacist will not dispense a drug or device pursuant to a prescription will allow a patient to, among other options, choose a pharmacy that will fulfill the patient's needs. Waiting in line just to be rejected will only delay access to a prescribed drug or device."

2) Real Issue. The stated goal of SB 644 and AB 2583 has been to ensure that a patient has access to their prescribed medications while preserving a licentiate's has the right to refuse to fill a prescription based on ethical, moral or religious objections. While the goal of the measures has been broad based, almost all of the discussions on the bills have been exclusively on women's access to emergency contraception (EC). If access to EC is the true goal of the legislation, then AB 2583 and related discussions should focus on EC. Currently the board receives fewer than two complaints a year relating to EC access. Given that there are approximately 30,000-licensed pharmacists in the state the actions the bill proposes to fix the problem access to EC appear to be premature.

3) Costs to the Board. The board estimates it would cost \$24,00 in fiscal year 2006-07 to comply with measure; annual cost thereafter would be approximately \$2,400 per fiscal year.

Fiscal Year 2006-07		
0.12 PY (AGPA) to create and gain approval for sign		
Initial Printing of 6,000 sign		\$12,000
Initial mailing cost (includes mailing tubes and postage \$2/sign)		\$12,000
Total		\$24,000
Annual Cost beyond 2007		
Print and mail 600 sign to newly licensed pharmacies		
Total		\$2,400

In cases where a pharmacy is newly licensed the board may include the sign in the same mailing tube as the Notice to Consumers required by B&P 4122; in this situation the cost would be considerably less and limited to the additional postage for additional weight of the sign in the mailing tube.

4) Suggested Amendments. (1) Specify in law the exact wording of the sign. (2) Require pharmacies, rather than the board, to print the sign. (3) Why is the sign needed if the point it for patients to get their medications due to protocol in B&P 733 (b)(3)(A)?

5) Previous Legislation. SB 644 (Chapter 417, Statutes of 2005) added B&P section 733 to the code to require a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. The board gained amendments to the measure that allows the board to cite and fine or issue letters of admonishment for violations of the measure's provisions.

6) Support / Opposition.

Support: California National Organization for Women

Opposition: Capitol Resource Institute
California Society of Health-System Pharmacists

7) History.

2006

- Apr. 19 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 9. Noes 3.) (April 18).
- Apr. 5 From committee: Do pass, and re-refer to Com. on HEALTH. Re-referred. (Ayes 6. Noes 2.) (April 4).
- Mar. 28 Re-referred to Com. on B. & P.
- Mar. 27 From committee chair, with author's amendments: Amend, and re-refer
- Mar. 20 Referred to Coms. on B. & P. and HEALTH
- Feb. 27 Read first time.
- Feb. 25 From printer. May be heard in committee March 27.
- Feb. 27 Read first time.
- Feb. 25 From printer. May be heard in committee March 27.
- Feb. 24 Introduced. To print.

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AMENDED IN ASSEMBLY MARCH 27, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2583

Introduced by Assembly Member Nation

February 24, 2006

An act to amend Section 733 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2583, as amended, Nation. Dispensing prescription drugs and devices: refusal to dispense.

Existing law prohibits a health care licentiate from obstructing a patient in obtaining a prescription drug or device, and requires the licentiate to dispense drugs and devices pursuant to a lawful prescription or order, except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate if certain requirements are met. Existing law authorizes the California State Board of Pharmacy to issue a citation for a violation of these provisions and authorizes its executive officer to issue a letter of admonishment for their violation.

This bill would require the board to create and provide a sign informing a patient of his or her right to timely access to a prescribed drug or device that a licentiate has refused to dispense based on ethical, moral, or religious grounds *and informing a patient of how to file a complaint with the board*. The bill would require licentiates authorized to make such a refusal, or their employers, to visibly place the sign at or near the entrance of the business.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 733 of the Business and Professions Code is amended to read:

733. (a) No licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other provision of law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription.

1 (A) A licentiate may decline to dispense a prescription drug or
2 device on this basis only if the licentiate has previously notified
3 his or her employer, in writing, of the drug or class of drugs to
4 which he or she objects, and the licentiate's employer can,
5 without creating undue hardship, provide a reasonable
6 accommodation of the licentiate's objection. The licentiate's
7 employer shall establish protocols that ensure that the patient has
8 timely access to the prescribed drug or device despite the
9 licentiate's refusal to dispense the prescription or order. For
10 purposes of this section, "reasonable accommodation" and
11 "undue hardship" shall have the same meaning as applied to
12 those terms pursuant to subdivision (I) of Section 12940 of the
13 Government Code.

14 (B) The California State Board of Pharmacy shall create and
15 provide to licentiates or licentiate's employers a sign informing
16 patients ~~that, if of the following:~~

17 (i) If a licentiate refuses to dispense a prescription drug or
18 device based on ethical, moral, or religious grounds, the patient
19 has a right to timely access to the prescribed drug or device. If

20 (ii) *How a patient may file a complaint with the board,*
21 *including providing contact information for the board.*

22 (C) If a licentiate is authorized, pursuant to subparagraph (A),
23 to decline to dispense a prescription drug or device, the licentiate
24 or licentiate's employer shall ~~place this sign~~ *the sign described in*
25 *subparagraph (B)* in a location that is visible to patients and that
26 is at or near the entrance of the business.

27 (c) For the purposes of this section, "prescription drug or
28 device" has the same meaning as the definition in Section 4022.

29 (d) The provisions of this section shall apply to the drug
30 therapy described in paragraph (8) of subdivision (a) of Section
31 4052.

32 (e) This section imposes no duty on a licentiate to dispense a
33 drug or device pursuant to a prescription or order without
34 payment for the drug or device, including payment directly by
35 the patient or through a third party payer accepted by the
36 licentiate or payment of any required copayment by the patient.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 2743

VERSION: INTRODUCED

AUTHOR: MATTHEWS

SPONSOR: CA. RETAILERS ASSOCIATION (CRA)

RECOMMENDED POSITION: NO POSITION

SUBJECT: PHARMACISTS: ANCILLARY PERSONNEL

Existing Law:

- 1) Limits the number of intern pharmacists a pharmacist can supervise at any one time to no more than two. (B&P 4114)
- 2) Limits the number of pharmacy technicians a pharmacy with only one pharmacist can have to no more than one. (B&P 4115)
- 3) Caps the ratio of pharmacists to pharmacy technicians for pharmacies with more than one pharmacist to no more than 2:1, after the first pharmacist (when a 1:1 ratio is required). (B&P 4115)
- 4) Limits the number of pharmacy technician trainees a pharmacist may supervise at any time to one. (B&P 4115)
- 5) Permits a pharmacist to determine the number of non-licensed personnel he or she may supervise that perform the duties of typing a prescription label or otherwise enter prescription information into a computer record system. (CCR 1793.3)

This Bill:

- 1) Limits number of ancillary personnel a pharmacy may have to no more than eight per pharmacist. (B&P 4115.3 Added)
- 2) Permits each pharmacist to have discretion as to how many ancillary personnel, within this limit, he or she supervises, subject to the limits set forth in B&P sections 4114, 4115, and 4115.5. (B&P 4115.3 Added)
- 2) Defines "ancillary personnel" to include pharmacy technicians, pharmacy technician trainees, interns, clerks, and typists. (B&P 4115.3 Added)

Comment:

1) Author's Intent. The author and sponsor's intent is to increase the pharmacy technician to pharmacist ratio allowed in a pharmacy. (The current ratio is 2:1 when there are two or more pharmacists in a pharmacy.) The sponsor hopes to achieve the increase by limiting the number of ancillary personnel allowed in a pharmacy. The sponsor is currently working with those that

may oppose the bill. If the sponsor is successful in eliminating opposition to the bill the bill will likely be amended to reflect a new pharmacy technician to pharmacist ratio and ancillary personnel to pharmacist ratio.

2) Board History on Issue. The board reviewed the issue of staffing ratios in the November 2001, *Pharmacy Manpower Task Force Report* and subsequently set the staffing ratio for community pharmacies at 4:1; that is one pharmacist may supervise up to two interns, one technician, and one technician in training. Subsequent legislation authorized a second and additional pharmacist to supervise two technicians (a ration of 5:1). The board removed a regulation on the limit on the number of clerk typist that a pharmacist may supervise.

3) Other States Pharmacy Technicians to Pharmacist Ratios. The staffing ratio of pharmacy technicians to pharmacist varies from state to state; seven states have a ratio of 4:1, three states have a ratio of 3:1, and fifteen states have a ratio similar to California's of 2:1.

4) Suggested Amendment. As currently drafted AB 2743 would restore the "clerk typist" ratio of staff a pharmacist may supervise. If the measure moves forward a definition of "clerk typist" should be amended into the bill.

5) History.

2006

Mar. 20	Referred to Com. on B. & P.
Feb. 25	From printer. May be heard in committee March 27.
Feb. 24	Introduced. To print.

ASSEMBLY BILL

No. 2743

Introduced by Assembly Member Matthews

February 24, 2006

An act to add Section 4115.3 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2743, as introduced, Matthews. Pharmacists: ancillary personnel.

Existing law, the Pharmacy Law, the violation of which is a crime, provides for the licensing and regulation of the practice of pharmacy by the California State Board of Pharmacy. Existing law provides that a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing specified tasks, and makes other provisions for the supervision of intern pharmacists, pharmacy technicians, and pharmacy technician trainees by a pharmacist.

This bill would prohibit a pharmacy from employing more than 8 ancillary personnel, as defined, per pharmacist. The bill would give a pharmacist discretion as to how many personnel he or she supervises, subject to the limits of existing law. Because this bill would create a new prohibition under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4115.3 is added to the Business and
2 Professions Code, to read:
3 4115.3. (a) A pharmacy shall have no more than eight
4 ancillary personnel per pharmacist. Each pharmacist shall have
5 individual discretion as to how many ancillary personnel, within
6 this limit, he or she supervises, subject to the limits set forth in
7 Sections 4114, 4115, and 4115.5.
8 (b) For purposes of this section, “ancillary personnel” includes
9 pharmacy technicians, pharmacy technician trainees, interns,
10 clerks, and typists.
11 SEC. 2. No reimbursement is required by this act pursuant to
12 Section 6 of Article XIII B of the California Constitution because
13 the only costs that may be incurred by a local agency or school
14 district will be incurred because this act creates a new crime or
15 infraction, eliminates a crime or infraction, or changes the
16 penalty for a crime or infraction, within the meaning of Section
17 17556 of the Government Code, or changes the definition of a
18 crime within the meaning of Section 6 of Article XIII B of the
19 California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 2986

VERSION: AMENDED APRIL 5, 2006

AUTHOR: MULLIN

SPONSOR: DEPARTMENT OF JUSTICE

RECOMMENDED POSITION: NO POSITION

SUBJECT: CONTROLLED SUBSTANCES: PRESCRIPTION REQUIREMENTS

Existing Law:

- 1) Describes the required security features of controlled substances prescription forms.
(H&S 11162.1)
- 2) Describes the required information that must be on a controlled substances prescription form for a person to fill, compound, or dispense a prescription for a controlled substance.
(H&S 11164)
- 3) Authorizes a prescriber or any agent of the prescriber on behalf of the prescriber to orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV.
(H&S 11164)
- 4) Requires DOJ to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for monitoring the prescribing and dispensing of Schedule II and III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.
(H&S 11165)
- 5) Requires pharmacies to report the following information to DOJ for Schedule II and III controlled substances: full name, address, gender, and date of birth of the patient; the prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility; pharmacy prescription number, license number, and federal controlled substance registration number; the NDC (National Drug Code) number of the controlled substance dispensed; the quantity of the controlled substance dispensed; the diagnosis code; date of the prescription and date of the dispensing the prescription.
(H&S 11165)
- 6) Permits a licensed health care practitioner eligible to prescribe Schedule II or III controlled substances or a pharmacist to make a written request for, and the DOJ to release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.
(H&S 11165.1)
- 7) Requires every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II to make a record that, as to the transaction, shows all of the information in H&S 11165.
(H&S 11190)

This Bill:

1) Requires secure tamper-resistant prescription forms to include the following preprinted information on the forms in addition to what is currently required:

- The name, address, and telephone number of the ultimate user or research subject, or the contact information as determined by the Secretary of the United States Department of Health and Human Services.
- Check boxes so that the prescriber must indicate the number of refills and whether the prescription is a first-time request.
- The date of origin of the prescription.

(H&S 11162.1 Amended)

2) Requires information listed in H&S 11162.1 to be on the security prescription form for a person to fill, compound, or dispense a prescription for a controlled substance. (H&S 11164 Amended)

3) Requires a dispensing pharmacy to provide DOJ the following information, in addition to what is currently required, for each Schedule II, III, or IV prescription it dispenses:

- The name, address, and telephone number of the ultimate user or research subject, or the contact information as determined by the Secretary of the United States Department of Health and Human Services.
- Check boxes so that the prescriber may indicate the number of refills and whether the prescription is a first time request.
- The date of origin of the prescription.

(H&S 11165 Amended)

4) Requires the CURES program to monitor and report the prescribing and dispensing of Schedule II, III, IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. (H&S 11165 and 11165.1 Amended)

5) Requires every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified as Schedule II to make a record that, as to the transaction, shows all of the information in H&S 11165. (H&S 11190 Amended)

6) Changes the controlled substances reporting requirement to DOJ from monthly to weekly. (H&S 11190 Amended)

Comment:

1) Author's Intent. The bill is sponsored the DOJ. The author's intent is to align California's Prescription Monitoring Program (PMP) with the federal National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER Act). This proposal will ensure state compliance with new federal mandates.

2) NASPER Act and CURES. The NASPER Act was signed into law by President Bush on August 11, 2005. The Act requires all states to establish a PMP or enhance their current state PMP.

The NASPER Act imposes several mandates not previously required by DOJ's Controlled Substances Utilization Review and Evaluation System (CURES) program. These mandates include:

- Capturing Schedule IV controlled substances data.
- Requiring dispensers to report to states within one week of each dispensing of a controlled substance

- Requiring specific data, such as patient telephone number, number of refills, and whether the prescription is for a refill or a first-time prescription.
- Requiring secure prescription forms include a refill notation; under current law this notation is optional at the prescriber's request.
- Requiring dispensers to report information in an electronic format specified by the U.S. Secretary of Health and Human Services, with an exception that the state may waive the required format with respect to individual dispensers.

3) Concerns with the Measure. The board reviewed AB 2986 as a legislative proposal at the board's meeting in February 2006. At that meeting discussion among board members and staff yielded two main concerns with the proposal as now contained in AB 2986, they are:

1. What happens if a patient cannot provide a telephone number or an address? (Can a pharmacist add this information?)
2. "Date of issue" versus "date of origin."

Not discussed at the meeting, but may be raised as a related issue is, is there a necessity to continue to use specialized prescription forms for controlled substances? This issue is raised in SB 1366, a related bill, that would amend overlapping sections of law delete the requirement that prescriptions for controlled substances be written on security printer prescription forms.

4) Related Legislation. SB 1366 (Aanestad) would eliminate the required use of specialized prescription forms by physicians and surgeons when issuing prescriptions for controlled substances. SB 1366 is set to be heard in the Senate Public Safety Committee on April 24, 2006.

5) Previous Legislation. SB 734 (Chapter 487, Statutes of 2005), sponsored the DOJ, provided clean-up changes to facilitate the effective operation of the CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement. Among other provisions the measure transferred the approval of security printers from the board to the DOJ. The board sought a technical amendment to cap board spending for CURES to the amount of money appropriated by the state budget.

SB 151 (Statutes of 2003, Chapter 406) implementing the "Pain Treatment and Diversion Act of 2003," the Controlled Substances Utilization Review and Evaluation System (CURES) became permanent.

AB 2018 (Chapter 1092, Statutes of 2002) provided changes to the triplicate pad and established a process for correction of prescription errors.

AB 2693 (Chapter 789, Statutes of 1998) exempted Schedule II controlled substances for patients with terminal illnesses from triplicate prescription form requirements.

AB 3042 (Chapter 738, Statutes of 1996) created the CURES program on a pilot basis.

6) Support / Opposition.

Support: Department of Justice (Sponsor)
California Narcotic Officers Association
Medical Board of California

Opposition: Association of Northern California Oncologists
California Medical Association

7) History.

2006

- Apr. 19 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 4. Noes 0.) (April 18).
- Apr. 6 Re-referred to Com. on PUB. S.
- Apr. 5 From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
- Mar. 23 Referred to Com. on PUB. S.
- Feb. 27 Read first time.
- Feb. 25 From printer. May be heard in committee March 27.
- Feb. 24 Introduced. To print.

AMENDED IN ASSEMBLY APRIL 5, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2986

Introduced by Assembly Member Mullin

February 24, 2006

An act to amend Sections 11162.1, 11164, 11165, 11165.1, and 11190 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2986, as amended, Mullin. Controlled substances: prescription requirements.

(1) Existing law provides that no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense such a prescription unless the prescription complies with specified requirements; the prescription must be printed with specified features and must set forth specified information. Unless otherwise specified, a violation of any of these provisions is a misdemeanor, punishable as specified.

This bill would require the prescription forms to also include the *name, address, and* telephone number of the ultimate user or research subject, or the contact information as determined by the U.S. Secretary of Health and Human Services; check boxes so that the prescriber may indicate ~~that a prescription is a first-time request or that a specified~~ the number of refills of the prescription have been ordered since the first prescription; and the date of origin of the ~~prescription and whether the prescription is a first-time request or a~~ *refill*.

(2) Existing law provides for the electronic monitoring and reporting of the prescribing and dispensing of Schedule II and Schedule III controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program.

This bill would provide that the CURES program shall also monitor and report on the prescribing and dispensing of Schedule IV controlled substances.

(3) Existing law provides that every practitioner, other than a pharmacist, who prescribes or administers a Schedule II controlled substance shall make a record of the transaction and shall provide the Department of Justice with information relating to the transaction on a monthly basis, as specified.

This bill would instead require the information to be provided to the Department of Justice on a weekly basis.

(4) The bill would make conforming changes to related provisions. By revising existing crimes, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 11162.1 of the Health and Safety Code
2 is amended to read:
3 11162.1. (a) The prescription forms for controlled substances
4 shall be printed with the following features:
5 (1) A latent, repetitive “void” pattern shall be printed across
6 the entire front of the prescription blank; if a prescription is
7 scanned or photocopied, the word “void” shall appear in a pattern
8 across the entire front of the prescription.
9 (2) A watermark shall be printed on the backside of the
10 prescription blank; the watermark shall consist of the words
11 “California Security Prescription.”

1 (3) A chemical void protection that prevents alteration by
2 chemical washing.

3 (4) A feature printed in thermo-chromic ink.

4 (5) An area of opaque writing so that the writing disappears if
5 the prescription is lightened.

6 (6) A description of the security features included on each
7 prescription form.

8 (7) (A) Six quantity check off boxes shall be printed on the
9 form and the following quantities shall appear:

10 1-24

11 25-49

12 50-74

13 75-100

14 101-150

15 151 and over.

16 (B) In conjunction with the quantity boxes, a space shall be
17 provided to designate the units referenced in the quantity boxes
18 when the drug is not in tablet or capsule form.

19 (8) Prescription blanks shall contain a statement printed on the
20 bottom of the prescription blank that the "Prescription is void if
21 the number of drugs prescribed is not noted."

22 (9) The preprinted name, category of licensure, license
23 number, federal controlled substance registration number of the
24 prescribing practitioner.

25 (10) The telephone number of the ultimate user or research
26 subject, or the contact information as determined by the
27 Secretary of the United States Department of Health and Human
28 Services.

29 (11) Check boxes shall be printed on the form so that the
30 ~~prescriber may indicate that a prescription is a first-time request~~
31 ~~or that a specified number of refills of the prescription have been~~
32 ~~ordered since the first prescription.~~ *prescriber may indicate the*
33 *number of refills ordered and whether the prescription is a*
34 *first-time request or a refill.*

35 (12) The date of origin of the prescription.

36 (13) A check box indicating the prescriber's order not to
37 substitute.

38 (14) An identifying number assigned to the approved security
39 printer by the Department of Justice.

1 (15) (A) A check box by the name of each prescriber when a
2 prescription form lists multiple prescribers.

3 (B) Each prescriber who signs the prescription form shall
4 identify himself or herself as the prescriber by checking the box
5 by their name.

6 (b) Each batch of controlled substance prescription forms shall
7 have the lot number printed on the form and each form within
8 that batch shall be numbered sequentially beginning with the
9 numeral one.

10 (c) (1) A prescriber designated by a licensed health care
11 facility, a clinic specified in Section 1200, or a clinic specified in
12 subdivision (a) of Section 1206 that has 25 or more physicians or
13 surgeons may order controlled substance prescription forms for
14 use by prescribers when treating patients in that facility without
15 the information required in paragraph (9) of subdivision (a) or
16 paragraph (3) of this subdivision.

17 (2) Forms ordered pursuant to this subdivision shall have the
18 name, category of licensure, license number, and federal
19 controlled substance registration number of the designated
20 prescriber and the name, address, category of licensure, and
21 license number of the licensed health care facility the clinic
22 specified in Section 1200, or the clinic specified in subdivision
23 (a) of Section 1206 that has 25 or more physicians or surgeons
24 preprinted on the form.

25 (3) Forms ordered pursuant to this section shall not be valid
26 prescriptions without the name, category of licensure, license
27 number, and federal controlled substance registration number of
28 the prescriber on the form.

29 (4) (A) Except as provided in subparagraph (B), the designated
30 prescriber shall maintain a record of the prescribers to whom the
31 controlled substance prescription forms are issued, that shall
32 include the name, category of licensure, license number, federal
33 controlled substance registration number, and the quantity of
34 controlled substance prescription forms issued to each prescriber
35 and be maintained in the health facility for three years.

36 (B) Forms ordered pursuant to this subdivision that are printed
37 by a computerized prescription generation system shall not be
38 subject to the requirements set forth in subparagraph (A) or
39 paragraph (7) of subdivision (a). Forms printed pursuant to this
40 subdivision that are printed by a computerized prescription

1 generation system may contain the prescriber's name, category of
2 professional licensure, license number, federal controlled
3 substance registration number, and the date of the prescription.

4 (d) This section shall become operative on July 1, 2004.

5 SEC. 2. Section 11164 of the Health and Safety Code is
6 amended to read:

7 11164. Except as provided in Section 11167, no person shall
8 prescribe a controlled substance, nor shall any person fill,
9 compound, or dispense a prescription for a controlled substance,
10 unless it complies with the requirements of this section.

11 (a) Each prescription for a controlled substance classified in
12 Schedule II, III, IV, or V, except as authorized by subdivision
13 (b), shall be made on a controlled substance prescription form as
14 specified in Section 11162.1 and shall meet the following
15 requirements:

16 (1) The prescription shall be signed and dated by the
17 prescriber in ink and shall contain the prescriber's address and
18 telephone number; the *name, address, and* telephone number of
19 the ultimate user or research subject, or contact information as
20 determined by the Secretary of the United States Department of
21 Health and Human Services; refill information, such as the
22 number of refills ordered and whether the prescription is a
23 first-time request or a refill; the date of origin of the prescription;
24 and the name, quantity, strength, and directions for use of the
25 controlled substance prescribed.

26 (2) The prescription shall also contain the address of the
27 person for whom the controlled substance is prescribed. If the
28 prescriber does not specify this address on the prescription, the
29 pharmacist filling the prescription or an employee acting under
30 the direction of the pharmacist shall write or type the address on
31 the prescription or maintain this information in a readily
32 retrievable form in the pharmacy.

33 (b) (1) Notwithstanding paragraph (1) of subdivision (a) of
34 Section 11162.1, any controlled substance classified in Schedule
35 III, IV, or V may be dispensed upon an oral or electronically
36 transmitted prescription, which shall be produced in hard copy
37 form and signed and dated by the pharmacist filling the
38 prescription or by any other person expressly authorized by
39 provisions of the Business and Professions Code. Any person
40 who transmits, maintains, or receives any electronically

1 transmitted prescription shall ensure the security, integrity,
2 authority, and confidentiality of the prescription.

3 (2) The date of issue of the prescription and all the information
4 required for a written prescription by subdivision (a) shall be
5 included in the written record of the prescription; the pharmacist
6 need not include the address, telephone number, license
7 classification, or federal registry number of the prescriber or the
8 address of the patient on the hard copy, if that information is
9 readily retrievable in the pharmacy.

10 (3) Pursuant to an authorization of the prescriber, any agent of
11 the prescriber on behalf of the prescriber may orally or
12 electronically transmit a prescription for a controlled substance
13 classified in Schedule III, IV, or V, if in these cases the written
14 record of the prescription required by this subdivision specifies
15 the name of the agent of the prescriber transmitting the
16 prescription.

17 (c) The use of commonly used abbreviations shall not
18 invalidate an otherwise valid prescription.

19 (d) Notwithstanding any provision of subdivisions (a) and (b),
20 prescriptions for a controlled substance classified in Schedule V
21 may be for more than one person in the same family with the
22 same medical need.

23 (e) This section shall become operative on January 1, 2005.

24 SEC. 3. Section 11165 of the Health and Safety Code is
25 amended to read:

26 11165. (a) To assist law enforcement and regulatory
27 agencies in their efforts to control the diversion and resultant
28 abuse of Schedule II, Schedule III, and Schedule IV controlled
29 substances, and for statistical analysis, education, and research,
30 the Department of Justice shall, contingent upon the availability
31 of adequate funds from the Contingent Fund of the Medical
32 Board of California, the Pharmacy Board Contingent Fund, the
33 State Dentistry Fund, the Board of Registered Nursing Fund, and
34 the Osteopathic Medical Board of California Contingent Fund,
35 maintain the Controlled Substance Utilization Review and
36 Evaluation System (CURES) for the electronic monitoring of the
37 prescribing and dispensing of Schedule II, Schedule III, and
38 Schedule IV controlled substances by all practitioners authorized
39 to prescribe or dispense these controlled substances.

1 (b) The reporting of Schedule III and Schedule IV controlled
2 substance prescriptions to CURES shall be contingent upon the
3 availability of adequate funds from the Department of Justice.
4 The Department of Justice may seek and use grant funds to pay
5 the costs incurred from the reporting of controlled substance
6 prescriptions to CURES. Funds shall not be appropriated from
7 the Contingent Fund of the Medical Board of California, the
8 Pharmacy Board Contingent Fund, the State Dentistry Fund, the
9 Board of Registered Nursing Fund, the Naturopathic Doctor's
10 Fund, or the Osteopathic Medical Board of California Contingent
11 Fund to pay the costs of reporting Schedule III and Schedule IV
12 controlled substance prescriptions to CURES.

13 (c) CURES shall operate under existing provisions of law to
14 safeguard the privacy and confidentiality of patients. Data
15 obtained from CURES shall only be provided to appropriate
16 state, local, and federal persons or public agencies for
17 disciplinary, civil, or criminal purposes and to other agencies or
18 entities, as determined by the Department of Justice, for the
19 purpose of educating practitioners and others in lieu of
20 disciplinary, civil, or criminal actions. Data may be provided to
21 public or private entities, as approved by the Department of
22 Justice, for educational, peer review, statistical, or research
23 purposes, provided that patient information, including any
24 information that may identify the patient, is not compromised.
25 Further, data disclosed to any individual or agency as described
26 in this subdivision shall not be disclosed, sold, or transferred to
27 any third party.

28 (d) For each prescription for a Schedule II, Schedule III, or
29 Schedule IV controlled substance, the dispensing pharmacy shall
30 provide the following information to the Department of Justice in
31 a frequency and format specified by the Department of Justice:

32 (1) Full name, address, *and the* telephone number of the
33 ultimate user or research subject, or contact information as
34 determined by the Secretary of the United States Department of
35 Health and Human Services, *and the* gender, and date of birth of
36 the patient.

37 (2) The prescriber's category of licensure and license number;
38 federal controlled substance registration number; and the state
39 medical license number of any prescriber using the federal

1 controlled substance registration number of a
2 government-exempt facility.

3 (3) Pharmacy prescription number, license number, and
4 federal controlled substance registration number.

5 (4) NDC (National Drug Code) number of the controlled
6 substance dispensed.

7 (5) Quantity of the controlled substance dispensed.

8 (6) ICD-9 (diagnosis code), if available.

9 (7) Number of refills ordered.

10 (8) Whether the drug was dispensed as a refill ~~or~~ of a
11 prescription or as a first-time request.

12 (9) Date of origin of the prescription.

13 (10) Date of dispensing of the prescription.

14 (e) This section shall become operative on January 1, 2005.

15 SEC. 4. Section 11165.1 of the Health and Safety Code is
16 amended to read:

17 11165.1. (a) (1) A licensed health care practitioner eligible
18 to prescribe Schedule II, Schedule III, or Schedule IV controlled
19 substances or a pharmacist may make a written request for, and
20 the Department of Justice may release to that practitioner or
21 pharmacist, the history of controlled substances dispensed to an
22 individual under his or her care based on data contained in
23 CURES.

24 (2) Any request for, or release of, a controlled substance
25 history pursuant to this section shall be made in accordance with
26 guidelines developed by the Department of Justice.

27 (b) In order to prevent the inappropriate, improper, or illegal
28 use of Schedule II, Schedule III, or Schedule IV controlled
29 substances, the Department of Justice may initiate the referral of
30 the history of controlled substances dispensed to an individual
31 based on data contained in CURES to licensed health care
32 practitioners, pharmacists, or both, providing care or services to
33 the individual.

34 (c) The history of controlled substances dispensed to an
35 individual based on data contained in CURES that is received by
36 a practitioner or pharmacist from the Department of Justice
37 pursuant to this section shall be considered medical information
38 subject to the provisions of the Confidentiality of Medical
39 Information Act contained in Part 2.6 (commencing with Section
40 56) of Division 1 of the Civil Code.

1 SEC. 5. Section 11190 of the Health and Safety Code is
2 amended to read:

3 11190. (a) Every practitioner, other than a pharmacist, who
4 prescribes or administers a controlled substance classified in
5 Schedule II shall make a record that, as to the transaction, shows
6 all of the following:

7 (1) The name and address of the patient.

8 (2) The date.

9 (3) The character, including the name and strength, and
10 quantity of controlled substances involved.

11 (b) The prescriber's record shall show the pathology and
12 purpose for which the controlled substance was administered or
13 prescribed.

14 (c) (1) For each prescription for a Schedule II or Schedule III
15 controlled substance that is dispensed by a prescriber pursuant to
16 Section 4170 of the Business and Professions Code, the
17 prescriber shall record and maintain the following information:

18 (A) Full name, address, *and the* telephone number of the
19 ultimate user or research subject, or contact information as
20 determined by the Secretary of the United States Department of
21 Health and Human Services, *and the* gender, and date of birth of
22 the patient.

23 (B) The prescriber's category of licensure and license number;
24 federal controlled substance registration number; and the state
25 medical license number of any prescriber using the federal
26 controlled substance registration number of a
27 government-exempt facility.

28 (C) NDC (National Drug Code) number of the controlled
29 substance dispensed.

30 (D) Quantity of the controlled substance dispensed.

31 (E) ICD-9 (diagnosis code), if available.

32 (F) Number of refills ordered.

33 (G) Whether the drug was dispensed as a refill of a
34 prescription or as a first-time request.

35 (H) Date of origin of the prescription.

36 (2) Each prescriber that dispenses controlled substances shall
37 provide the Department of Justice the information required by
38 this subdivision on a weekly basis in a format set by the
39 Department of Justice pursuant to regulation.

40 (d) This section shall become operative on January 1, 2005.

1 SEC. 6. No reimbursement is required by this act pursuant to
2 Section 6 of Article XIII B of the California Constitution because
3 the only costs that may be incurred by a local agency or school
4 district will be incurred because this act creates a new crime or
5 infraction, eliminates a crime or infraction, or changes the
6 penalty for a crime or infraction, within the meaning of Section
7 17556 of the Government Code, or changes the definition of a
8 crime within the meaning of Section 6 of Article XIII B of the
9 California Constitution.

O



CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: SB 1366

VERSION: AMENDED APRIL 4, 2006

AUTHOR: AANESTAD

SPONSOR: CALIFORNIA MEDICAL ASSOCIATION

RECOMMENDED POSITION: NEUTRAL

SUBJECT: CONTROLLED SUBSTANCES: SPECIALIZED PRESCRIPTION PADS

Existing Law:

- 1) Requires physicians and surgeons to obtain and use forms for controlled substances from printers that have been approved by the Department of Justice when prescribing controlled substances. (H&S 11161.5)
- 2) Specifies the preprinted requirements for controlled substances forms. (H&S 11162.1)
- 3) Specifies the type of information that is required to be filled in on a prescription for schedule II-V drugs. (H&S 11162.1)

This Bill:

- 1) Eliminates the required use of specialized secure prescription pads for prescribing all scheduled drugs. As such, requirements to license security printers are also repealed.
(H&S 11161, 11161.7, 11162.6, 11167 Amended, 11161.5, 11162.1 Repealed)
- 2) Retains the requirements that prescriptions for Schedule II-V drugs contain specified information, such as the prescription shall be signed and dated by the prescriber, in ink and shall contain the prescriber's address and telephone number; the name of the person for whom the controlled substance is prescribed; and the name, quantity, strength, and directions for use of the controlled substance prescribed. (H&S 11164 Amended)
- 3) Repeals the terminally ill or H&S 11159.2 exemption prescriptions. Repeals the requirement that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements. (H&S 11159.2 Repealed)
- 4) Eliminates the requirement that the board must notify security printers when a prescriber's authority to prescribe controlled substances is restricted by law enforcement or licensing board. (H&S 11161.7 Amended)

Comment:

1) Author's Intent. The author's intent is to eliminate special prescription forms for prescribing controlled substance drugs, because in part, there is no evidence available to show that the use of specialized pads has reduced the level of illegal use or dissemination of controlled drugs. The author believes the public is better served by tracking controlled substances through the

Controlled Substance Utilization Review and Evaluation System (CURES) electronic surveillance system.

2) Brief History of Controlled Substance Forms and Tracking in CA. In 1939, California became the first state to institute the use of specialized triplicate prescription forms to stem the abuse of selected dangerous drugs. Over the years the types of prescribed drugs requiring a triplicate form was expanded to include Schedule II-V drugs. In 2004, SB 151 eliminated the requirement for the use of triplicate forms and replaced it with a requirement to use new security printer forms issued by licensed printers.

In 1996, CURES was created to electronically monitor the prescribing, dispensing, and use of schedule II drugs. While this program initiated as a pilot program it has since become a permanent program and been expanded to track schedule II and III drugs.

In 2006, California has the distinction of being one of three states that still requires the use of specialized prescription forms for prescribing schedule drugs (see attached chart). Most other states have moved away from the specialized forms and rely on CURES, like monitoring programs to identify the misuse and abuse of scheduled drugs.

3) Related Legislation. AB 2986 (Mullin) Controlled substances, prescription requirements, sponsored by the Department of Justice, would require security prescription forms to also include the telephone number of the ultimate user or research subject, or the contact information as determined by the U.S. Secretary of Health and Human Services; check boxes so that the prescriber may indicate that a prescription is a first-time request or that a specified number of refills of the prescription have been ordered since the first prescription; and the date of origin of the prescription.

4) Previous Legislation.

SB 734 (Chapter 487, Statutes of 2005) made clean-up changes to facilitate the effective operation of the CURES, the prescribing and dispensing of controlled substances, and the program duties of the Bureau of Narcotics Enforcement. Among other provisions it transferred the approval of security printers from the board to the Department of Justice.

SB 151 (Chapter 406, Statutes of 2003) implementing the "Pain Treatment and Diversion Act of 2003," the Controlled Substances Utilization Review and Evaluation System (CURES) became permanent.

AB 2018 (Chapter 1092, Statutes of 2002) provided changes to the triplicate pad and established a process for correction of prescription errors.

AB 2693 (Chapter 789, Statutes of 1998) exempted Schedule II controlled substances for patients with terminal illnesses from triplicate prescription form requirements.

AB 3042 (Chapter 738, Statutes of 1996) created the CURES program on a pilot basis.

5) History.

2006

Apr. 6 Set for hearing April 25.

Apr. 5 Re-referred to Com. on PUB. S.

Apr. 4 From committee with author's amendments. Read second time. Amended. Re-referred to committee.

Mar. 2 To Com. on RLS.

Feb. 22 From print. May be acted upon on or after March 24.

Feb. 21 Introduced. Read first time. To Com. on RLS. for assignment. To print.

STATES WITH PRESCRIPTION MONITORING PROGRAMS
January 2006

	STATE	PROGRAM TYPE	SCHEDULES COVERED	YEAR ENACTED
1	AL	Electronic	C II - V	2004
2	CO	Electronic	C II - V	2005
3	CA	Single-Copy Serialized Electronic	C II - V	2005
4	HI	Electronic	C II - IV	2002
5	ID	Electronic	C II - V	2001
6	IL	Electronic	C II	1999
7	IN	Electronic	C II - V	2004
8	KY	Electronic	C II - V	1998
9	ME	Electronic	C II - IV	2003
10	MA	Electronic	C II	1992
11	MI	Electronic	C II - V	2002
12	NC	Electronic	C II - V	2005
13	NM	Electronic	C II - IV	2004
14	NV	Electronic	C II - IV	1995
15	NY	Single-copy, serialized/Electronic (state-issued)	C II, Benzos	1998
16	OH	Electronic	C II - V	2005
17	OK	Electronic	C II	1990
18	RI	Electronic	C II, III	1997
19	TN	Electronic	C II - IV	2002
20	TX	Single-copy, serialized/Electronic (state-issued)	C II	1997
21	UT	Electronic	C II - V	1995
22	VA	Electronic	C II - V	2002
23	WV	Electronic	C II - IV	1995

AMENDED IN SENATE APRIL 4, 2006

SENATE BILL

No. 1366

Introduced by Senator Aanestad

February 21, 2006

An act to amend Sections 11159.2, 11161, 11162.6, 11164, 11164.1, 11165, 11167, and 11167.5 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 1366, as amended, Aanestad. Controlled substances.

~~Existing law regulates the prescription of controlled substances, as specified:~~

~~This bill would make technical, nonsubstantive changes to these provisions:~~

Existing law requires an authorized prescriber to write prescriptions for controlled substances on a specialized secured prescription form, and makes exceptions therefore.

This bill would remove the requirement that authorized persons write prescriptions for controlled substances on a specialized secured prescription form and delete the exceptions therefore.

Existing law allows a court to require a prescriber to turn over his or her specialized secured prescription forms for controlled substances when the prescriber is charged with a specified felony offense.

This bill would allow the court to issue an order prohibiting the prescriber from prescribing controlled substances when the prescriber is charged with a specified felony offense. Because a violation of this requirement would be a crime, the bill would impose a state-mandated local program.

Existing law makes it a crime to counterfeit a secured controlled substance prescription form.

This bill would repeal that crime.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~-yes.
State-mandated local program: ~~no~~-yes.

The people of the State of California do enact as follows:

1 ~~SECTION 1. Section 11159.2 of the Health and Safety Code~~
2 ~~is amended to read:~~

3 ~~11159.2. (a) Notwithstanding any other provision of law, a~~
4 ~~prescription for a controlled substance for use by a patient who~~
5 ~~has a terminal illness may be written on a prescription form that~~
6 ~~does not meet the requirements of Section 11162.1 if the~~
7 ~~prescription meets the following requirements:~~

8 ~~(1) Contain the information specified in subdivision (a) of~~
9 ~~Section 11164.~~

10 ~~(2) Indicate that the prescriber has certified that the patient is~~
11 ~~terminally ill by the words "11159.2 exemption."~~

12 ~~(b) A pharmacist may fill a prescription pursuant to this~~
13 ~~section when there is a technical error in the certification~~
14 ~~required by paragraph (2) of subdivision (a), provided that he or~~
15 ~~she has personal knowledge of the patient's terminal illness, and~~
16 ~~subsequently returns the prescription to the prescriber for~~
17 ~~correction within 72 hours.~~

18 ~~(c) For purposes of this section, "terminally ill" means a~~
19 ~~patient who meets all of the following conditions:~~

20 ~~(1) In the reasonable medical judgment of the prescribing~~
21 ~~physician, the patient has been determined to be suffering from~~
22 ~~an illness that is incurable and irreversible.~~

23 ~~(2) In the reasonable medical judgment of the prescribing~~
24 ~~physician, the patient's illness will, if the illness takes its normal~~
25 ~~course, bring about the death of the patient within a period of one~~
26 ~~year.~~

1 ~~(3) The patient's treatment by the physician prescribing a~~
2 ~~controlled substance pursuant to this section primarily is for the~~
3 ~~control of pain, symptom management, or both, rather than for~~
4 ~~cure of the illness.~~

5 ~~SECTION 1. Section 11159.2 of the Health and Safety Code~~
6 ~~is repealed.~~

7 ~~11159.2. (a) Notwithstanding any other provision of law, a~~
8 ~~prescription for a controlled substance for use by a patient who~~
9 ~~has a terminal illness may be written on a prescription form that~~
10 ~~does not meet the requirements of Section 11162.1 if the~~
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26 ~~an illness that is incurable and irreversible.~~

27 ~~(2) In the reasonable medical judgment of the prescribing~~
28 ~~physician, the patient's illness will, if the illness takes its normal~~
29 ~~course, bring about the death of the patient within a period of one~~
30 ~~year.~~

31 ~~(3) The patient's treatment by the physician prescribing a~~
32 ~~controlled substance pursuant to this section primarily is for the~~
33 ~~control of pain, symptom management, or both, rather than for~~
34 ~~cure of the illness.~~

35 ~~(d) This section shall become operative on July 1, 2004.~~

36 ~~SEC. 2. Section 11161 of the Health and Safety Code is~~
37 ~~amended to read:~~

38 ~~11161. (a) When a practitioner is named in a warrant of~~
39 ~~arrest or is charged in an accusatory pleading with a felony~~
40 ~~violation of Section 11153, 11154, 11156, 11157, 11170, 11173,~~

1 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5,
2 11379, 11379.5, or 11379.6, the court in which the accusatory
3 pleading is filed or the magistrate who issued the warrant of
4 arrest shall, upon the motion of a law enforcement agency which
5 is supported by reasonable cause, issue an order ~~which requires~~
6 ~~the practitioner to surrender to the clerk of the court all controlled~~
7 ~~substance prescription forms in the practitioner's possession at a~~
8 ~~time set in the order and which prohibits the practitioner from~~
9 ~~obtaining, ordering, or using any additional prescription forms.~~
10 *prohibiting the practitioner from prescribing controlled*
11 *substances.* The law enforcement agency obtaining the order
12 shall notify the Department of Justice of this order. Except as
13 provided in subdivisions (b) and (e) of this section, the order
14 shall remain in effect until further order of the court. Any
15 practitioner ~~possessing prescription forms who prescribes~~
16 *controlled substances* in violation of the order is guilty of a
17 misdemeanor.

18 (b) The order provided by subdivision (a) shall be vacated if
19 the court or magistrate finds that the underlying violation or
20 violations are not supported by reasonable cause at a hearing held
21 within two court days after the practitioner files and personally
22 serves upon the prosecuting attorney and the law enforcement
23 agency that obtained the order, a notice of motion to vacate the
24 order with any affidavits on which the practitioner relies. At the
25 hearing, the burden of proof, by a preponderance of the evidence,
26 is on the prosecution. Evidence presented at the hearing shall be
27 limited to the warrant of arrest with supporting affidavits, the
28 motion to ~~require prohibit~~ the defendant ~~to surrender controlled~~
29 ~~substance prescription forms and to prohibit the defendant from~~
30 ~~obtaining, ordering, or using controlled substance prescription~~
31 ~~forms, with from prescribing controlled substances with~~
32 supporting affidavits, the sworn complaint together with any
33 documents or reports incorporated by reference thereto which, if
34 based on information and belief, state the basis for the
35 information, or any other documents of similar reliability as well
36 as affidavits and counter affidavits submitted by the prosecution
37 and defense. Granting of the motion to vacate the order is no bar
38 to prosecution of the alleged violation or violations.

39 (c) The defendant may elect to challenge the order issued
40 under subdivision (a) at the preliminary examination. At that

1 hearing, the evidence shall be limited to that set forth in
2 subdivision (b) and any other evidence otherwise admissible at
3 the preliminary examination.

4 (d) If the practitioner has not moved to vacate the order issued
5 under subdivision (a) by the time of the preliminary examination
6 and he or she is held to answer on the underlying violation or
7 violations, the practitioner shall be precluded from afterwards
8 moving to vacate the order. If the defendant is not held to answer
9 on the underlying charge or charges at the conclusion of the
10 preliminary examination, the order issued under subdivision (a)
11 shall be vacated.

12 (e) Notwithstanding subdivision (d), any practitioner who is
13 diverted pursuant to Chapter 2.5 (commencing with Section
14 1000) of Title 7 of Part 2 of the Penal Code may file a motion to
15 vacate the order issued under subdivision (a).

16 *SEC. 3. Section 11161.5 of the Health and Safety Code is*
17 *repealed.*

18 ~~11161.5. (a) Prescription forms for controlled substance~~
19 ~~prescriptions shall be obtained from security printers approved~~
20 ~~by the Department of Justice.~~

21 ~~(b) The department may approve security printer applications~~
22 ~~after the applicant has provided the following information:~~

23 ~~(1) Name, address, and telephone number of the applicant.~~

24 ~~(2) Policies and procedures of the applicant for verifying the~~
25 ~~identity of the prescriber ordering controlled substance~~
26 ~~prescription forms.~~

27 ~~(3) Policies and procedures of the applicant for verifying~~
28 ~~delivery of controlled substance prescription forms to~~
29 ~~prescribers.~~

30 ~~(4) (A) The location, names, and titles of the applicant's agent~~
31 ~~for service of process in this state; all principal corporate officers,~~
32 ~~if any; and all managing general partners, if any.~~

33 ~~(B) A report containing this information shall be made on an~~
34 ~~annual basis and within 30 days after any change of office,~~
35 ~~principal corporate officers, or managing general partner.~~

36 ~~(5) (A) A signed statement indicating whether the applicant,~~
37 ~~principal corporate officers, or managing general partners have~~
38 ~~ever been convicted of, or pled no contest to, a violation of any~~
39 ~~law of a foreign country, the United States, or any state, or of any~~
40 ~~local ordinance.~~

1 ~~(B) The department shall provide the applicant with the means~~
2 ~~and direction to provide fingerprints and related information, in a~~
3 ~~manner specified by the department, for the purpose of~~
4 ~~completing state, federal, or foreign criminal background checks.~~

5 ~~(C) Any applicant described in subdivision (b) shall submit his~~
6 ~~or her fingerprint images and related information to the~~
7 ~~department, for the purpose of the department obtaining~~
8 ~~information as to the existence and nature of a record of state,~~
9 ~~federal, or foreign level convictions and state, federal, or foreign~~
10 ~~level arrests for which the department establishes that the~~
11 ~~applicant was released on bail or on his or her own recognizance~~
12 ~~pending trial, as described in subdivision (I) of Section 11105 of~~
13 ~~the Penal Code. Requests for federal level criminal offender~~
14 ~~record information received by the department pursuant to this~~
15 ~~section shall be forwarded to the Federal Bureau of Investigation~~
16 ~~by the department.~~

17 ~~(D) The department shall assess against each applicant a fee~~
18 ~~determined by the department to be sufficient to cover all~~
19 ~~processing, maintenance, and investigative costs generated from~~
20 ~~or associated with completing state, federal, or foreign~~
21 ~~background checks pursuant to this section with respect to that~~
22 ~~applicant; the fee shall be paid by the applicant at the time he or~~
23 ~~she submits fingerprints and related information to the~~
24 ~~department.~~

25 ~~(E) The department shall retain fingerprint impressions and~~
26 ~~related information for subsequent arrest notification pursuant to~~
27 ~~Section 11105.2 of the Penal Code for all applicants.~~

28 ~~(e) The department may, within 60 calendar days of receipt of~~
29 ~~the application from the applicant, deny the security printer~~
30 ~~application.~~

31 ~~(d) The department may deny a security printer application on~~
32 ~~any of the following grounds:~~

33 ~~(1) The applicant, any individual owner, partner, corporate~~
34 ~~officer, manager, agent, representative, employee, or~~
35 ~~subcontractor for the applicant, who has direct access,~~
36 ~~management, or control of controlled substance prescription~~
37 ~~forms, has been convicted of a crime. A conviction within the~~
38 ~~meaning of this paragraph means a plea or verdict of guilty or a~~
39 ~~conviction following a plea of nolo contendere. Any action~~
40 ~~which a board is permitted to take following the establishment of~~

1 a conviction may be taken when the time for appeal has elapsed;
2 the judgment of conviction has been affirmed on appeal, or when
3 an order granting probation is made suspending the imposition of
4 sentence, irrespective of a subsequent order under the provisions
5 of Section 1203.4 of the Penal Code.

6 (2) ~~The applicant committed any act involving dishonesty,~~
7 ~~fraud, or deceit with the intent to substantially benefit himself,~~
8 ~~herself, or another, or substantially injure another.~~

9 (3) ~~The applicant committed any act that would constitute a~~
10 ~~violation of this division.~~

11 (4) ~~The applicant knowingly made a false statement of fact~~
12 ~~required to be revealed in the application to produce controlled~~
13 ~~substance prescription forms.~~

14 (5) ~~The department determines that the applicant failed to~~
15 ~~demonstrate adequate security procedures relating to the~~
16 ~~production and distribution of controlled substance prescription~~
17 ~~forms.~~

18 (6) ~~The department determines that the applicant has~~
19 ~~submitted an incomplete application.~~

20 (7) ~~As a condition for its approval as a security printer, an~~
21 ~~applicant shall authorize the Department of Justice to make any~~
22 ~~examination of the books and records of the applicant, or to visit~~
23 ~~and inspect the applicant during business hours, to the extent~~
24 ~~deemed necessary by the board or department to properly enforce~~
25 ~~this section.~~

26 (e) ~~An approved applicant shall submit an exemplar of a~~
27 ~~controlled substance prescription form, with all security features,~~
28 ~~to the Department of Justice within 30 days of initial production.~~

29 (f) ~~The department shall maintain a list of approved security~~
30 ~~printers and the department shall make this information available~~
31 ~~to prescribers and other appropriate government agencies,~~
32 ~~including the Board of Pharmacy.~~

33 (g) ~~Before printing any controlled substance prescription~~
34 ~~forms, a security printer shall verify with the appropriate~~
35 ~~licensing board that the prescriber possesses a license and current~~
36 ~~prescribing privileges which permits the prescribing of controlled~~
37 ~~substances.~~

38 (h) ~~Controlled substance prescription forms shall be provided~~
39 ~~directly to the prescriber either in person, by certified mail, or by~~

1 ~~a means that requires a signature signifying receipt of the~~
2 ~~package and provision of that signature to the security printer.~~

3 ~~(i) Security printers shall retain ordering and delivery records~~
4 ~~in a readily retrievable manner for individual prescribers for three~~
5 ~~years.~~

6 ~~(j) Security printers shall produce ordering and delivery~~
7 ~~records upon request by an authorized officer of the law as~~
8 ~~defined in Section 4017 of the Business and Professions Code.~~

9 ~~(k) (1) The department may revoke its approval of a security~~
10 ~~printer for a violation of this division or action that would permit~~
11 ~~a denial pursuant to subdivision (d) of this section.~~

12 ~~(2) When the department revokes its approval, it shall notify~~
13 ~~the appropriate licensing boards and remove the security printer~~
14 ~~from the list of approved security printers.~~

15 *SEC. 4. Section 11161.7 of the Health and Safety Code is*
16 *amended to read:*

17 11161.7. (a) When a prescriber's authority to prescribe
18 controlled substances is restricted by civil, criminal, or
19 administrative action, or by an order of the court issued pursuant
20 to Section 11161, the law enforcement agency or licensing board
21 that sought the restrictions shall provide the name, category of
22 licensure, license number, and the nature of the restrictions
23 imposed on the prescriber to ~~security printers~~, the Department of
24 Justice; and the Board of Pharmacy.

25 (b) The Board of Pharmacy shall make available the
26 information required by subdivision (a) to pharmacies and
27 ~~security printers~~ to prevent the dispensing of controlled substance
28 prescriptions issued by the prescriber ~~and the ordering of~~
29 ~~additional controlled substance prescription forms by the~~
30 ~~restricted prescriber.~~

31 *SEC. 5. Section 11162.1 of the Health and Safety Code is*
32 *repealed.*

33 ~~11162.1. (a) The prescription forms for controlled substances~~
34 ~~shall be printed with the following features:~~

35 ~~(1) A latent, repetitive "void" pattern shall be printed across~~
36 ~~the entire front of the prescription blank; if a prescription is~~
37 ~~scanned or photocopied, the word "void" shall appear in a pattern~~
38 ~~across the entire front of the prescription.~~

1 ~~(2) A watermark shall be printed on the backside of the~~
2 ~~prescription blank; the watermark shall consist of the words~~
3 ~~“California Security Prescription.”~~

4 ~~(3) A chemical void protection that prevents alteration by~~
5 ~~chemical washing.~~

6 ~~(4) A feature printed in thermo-chromic ink.~~

7 ~~(5) An area of opaque writing so that the writing disappears if~~
8 ~~the prescription is lightened.~~

9 ~~(6) A description of the security features included on each~~
10 ~~prescription form.~~

11 ~~(7) (A) Six quantity check off boxes shall be printed on the~~
12 ~~form and the following quantities shall appear:~~

13 ~~1-24~~

14 ~~25-49~~

15 ~~50-74~~

16 ~~75-100~~

17 ~~101-150~~

18 ~~151 and over.~~

19 ~~(B) In conjunction with the quantity boxes, a space shall be~~
20 ~~provided to designate the units referenced in the quantity boxes~~
21 ~~when the drug is not in tablet or capsule form.~~

22 ~~(8) Prescription blanks shall contain a statement printed on the~~
23 ~~bottom of the prescription blank that the “Prescription is void if~~
24 ~~the number of drugs prescribed is not noted.”~~

25 ~~(9) The preprinted name, category of licensure, license~~
26 ~~number, federal controlled substance registration number of the~~
27 ~~prescribing practitioner.~~

28 ~~(10) A check box indicating the prescriber’s order not to~~
29 ~~substitute.~~

30 ~~(11) An identifying number assigned to the approved security~~
31 ~~printer by the Department of Justice.~~

32 ~~(12) (A) A check box by the name of each prescriber when a~~
33 ~~prescription form lists multiple prescribers.~~

34 ~~(B) Each prescriber who signs the prescription form shall~~
35 ~~identify himself or herself as the prescriber by checking the box~~
36 ~~by their name.~~

37 ~~(b) Each batch of controlled substance prescription forms shall~~
38 ~~have the lot number printed on the form and each form within~~
39 ~~that batch shall be numbered sequentially beginning with the~~
40 ~~numeral one.~~

1 ~~(c) (1) A prescriber designated by a licensed health care~~
2 ~~facility, a clinic specified in Section 1200, or a clinic specified in~~
3 ~~subdivision (a) of Section 1206 that has 25 or more physicians or~~
4 ~~surgeons may order controlled substance prescription forms for~~
5 ~~use by prescribers when treating patients in that facility without~~
6 ~~the information required in paragraph (9) of subdivision (a) or~~
7 ~~paragraph (3) of this subdivision.~~

8 ~~(2) Forms ordered pursuant to this subdivision shall have the~~
9 ~~name, category of licensure, license number, and federal~~
10 ~~controlled substance registration number of the designated~~
11 ~~prescriber and the name, address, category of licensure, and~~
12 ~~license number of the licensed health care facility the clinic~~
13 ~~specified in Section 1200, or the clinic specified in subdivision~~
14 ~~(a) of Section 1206 that has 25 or more physicians or surgeons~~
15 ~~preprinted on the form.~~

16 ~~(3) Forms ordered pursuant to this section shall not be valid~~
17 ~~prescriptions without the name, category of licensure, license~~
18 ~~number, and federal controlled substance registration number of~~
19 ~~the prescriber on the form.~~

20 ~~(4) (A) Except as provided in subparagraph (B), the designated~~
21 ~~prescriber shall maintain a record of the prescribers to whom the~~
22 ~~controlled substance prescription forms are issued, that shall~~
23 ~~include the name, category of licensure, license number, federal~~
24 ~~controlled substance registration number, and the quantity of~~
25 ~~controlled substance prescription forms issued to each prescriber~~
26 ~~and be maintained in the health facility for three years.~~

27 ~~(B) Forms ordered pursuant to this subdivision that are printed~~
28 ~~by a computerized prescription generation system shall not be~~
29 ~~subject to the requirements set forth in subparagraph (A) or~~
30 ~~paragraph (7) of subdivision (a). Forms printed pursuant to this~~
31 ~~subdivision that are printed by a computerized prescription~~
32 ~~generation system may contain the prescriber's name, category of~~
33 ~~professional licensure, license number, federal controlled~~
34 ~~substance registration number, and the date of the prescription.~~

35 ~~(d) This section shall become operative on July 1, 2004.~~

36 ~~SEC. 3.~~

37 ~~SEC. 6. Section 11162.6 of the Health and Safety Code is~~
38 ~~amended to read:~~

39 ~~11162.6. (a) Every person who counterfeits a controlled~~
40 ~~substance prescription form shall be guilty of a misdemeanor~~

1 punishable by imprisonment in a county jail for not more than
2 one year, by a fine not exceeding one thousand dollars (\$1,000),
3 or by both that imprisonment and fine.

4 (b) ~~Every person who knowingly possesses a counterfeited~~
5 ~~controlled substance prescription form shall be guilty of a~~
6 ~~misdemeanor punishable by imprisonment in a county jail not~~
7 ~~exceeding six months, by a fine not exceeding one thousand~~
8 ~~dollars (\$1,000), or by both that imprisonment and fine.~~

9 (c) ~~Every person who attempts to obtain or obtains a~~
10 ~~controlled substance prescription form under false pretenses shall~~
11 ~~be guilty of a misdemeanor punishable by imprisonment in a~~
12 ~~county jail not exceeding six months, by a fine not exceeding one~~
13 ~~thousand dollars (\$1,000), or by both that imprisonment and fine.~~

14 (d) ~~Every person who fraudulently produces controlled~~
15 ~~substance prescription forms shall be guilty of a misdemeanor~~
16 ~~punishable by imprisonment in a county jail not exceeding six~~
17 ~~months, by a fine not exceeding one thousand dollars (\$1,000), or~~
18 ~~by both that imprisonment and fine.~~

19 SEC. 4.

20 SEC. 7. Section 11164 of the Health and Safety Code is
21 amended to read:

22 11164. Except as provided in Section 11167, no person shall
23 prescribe a controlled substance, nor shall any person fill,
24 compound, or dispense a prescription for a controlled substance,
25 unless it complies with the requirements of this section.

26 (a) Each prescription for a controlled substance classified in
27 Schedule II, III, IV, or V, except as authorized by subdivision
28 (b), ~~shall be made on a controlled substance prescription form as~~
29 ~~specified in Section 11162.1 and~~ shall meet the following
30 requirements:

31 (1) The prescription shall be signed and dated by the
32 prescriber in ink and shall contain the prescriber's address and
33 telephone number; the name of the person for whom the
34 controlled substance is prescribed; and the name, quantity,
35 strength, and directions for use of the controlled substance
36 prescribed.

37 (2) The prescription shall also contain the address of the
38 person for whom the controlled substance is prescribed. If the
39 prescriber does not specify this address on the prescription, the
40 pharmacist filling the prescription or an employee acting under

1 the direction of the pharmacist shall write or type the address on
2 the prescription or maintain this information in a readily
3 retrievable form in the pharmacy.

4 (b) (1) Notwithstanding paragraph (1) of subdivision (a) of
5 Section 11162.1, any controlled substance classified in Schedule
6 III, IV, or V may be dispensed upon an oral or electronically
7 transmitted prescription, which shall be produced in hard copy
8 form and signed and dated by the pharmacist filling the
9 prescription or by any other person expressly authorized by
10 provisions of the Business and Professions Code. Any person
11 who transmits, maintains, or receives any electronically
12 transmitted prescription shall ensure the security, integrity,
13 authority, and confidentiality of the prescription.

14 (2) The date of issue of the prescription and all the information
15 required for a written prescription by subdivision (a) shall be
16 included in the written record of the prescription; the pharmacist
17 need not include the address, telephone number, license
18 classification, or federal registry number of the prescriber or the
19 address of the patient on the hard copy, if that information is
20 readily retrievable in the pharmacy.

21 (3) Pursuant to an authorization of the prescriber, any agent of
22 the prescriber on behalf of the prescriber may orally or
23 electronically transmit a prescription for a controlled substance
24 classified in Schedule III, IV, or V, if in these cases the written
25 record of the prescription required by this subdivision specifies
26 the name of the agent of the prescriber transmitting the
27 prescription.

28 (c) The use of commonly used abbreviations shall not
29 invalidate an otherwise valid prescription.

30 (d) Notwithstanding any provision of subdivisions (a) and (b),
31 prescriptions for a controlled substance classified in Schedule V
32 may be for more than one person in the same family with the
33 same medical need.

34 ~~SEC. 5.~~

35 *SEC. 8.* Section 11164.1 of the Health and Safety Code is
36 amended to read:

37 11164.1. (a) (1) Notwithstanding any other provision of
38 law, a prescription for a controlled substance issued by a
39 prescriber in another state for delivery to a patient in another
40 state may be dispensed by a California pharmacy, if the

1 prescription conforms with the requirements for controlled
2 substance prescriptions in the state in which the controlled
3 substance was prescribed.

4 (2) All prescriptions for Schedule II and Schedule III
5 controlled substances dispensed pursuant to this subdivision shall
6 be reported by the dispensing pharmacy to the Department of
7 Justice in the manner prescribed by subdivision (d) of Section
8 11165.

9 (b) Pharmacies may dispense prescriptions for Schedule III,
10 Schedule IV, and Schedule V controlled substances from
11 out-of-state prescribers pursuant to Section 4005 of the Business
12 and Professions Code and Section 1717 of Title 16 of the
13 California Code of Regulations.

14 ~~SEC. 6.~~

15 *SEC. 9.* Section 11165 of the Health and Safety Code is
16 amended to read:

17 11165. (a) To assist law enforcement and regulatory
18 agencies in their efforts to control the diversion and resultant
19 abuse of Schedule II and Schedule III controlled substances, and
20 for statistical analysis, education, and research, the Department
21 of Justice shall, contingent upon the availability of adequate
22 funds from the Contingent Fund of the Medical Board of
23 California, the Pharmacy Board Contingent Fund, the State
24 Dentistry Fund, the Board of Registered Nursing Fund, and the
25 Osteopathic Medical Board of California Contingent Fund,
26 maintain the Controlled Substance Utilization Review and
27 Evaluation System (CURES) for the electronic monitoring of the
28 prescribing and dispensing of Schedule II and Schedule III
29 controlled substances by all practitioners authorized to prescribe
30 or dispense these controlled substances.

31 (b) The reporting of Schedule III controlled substance
32 prescriptions to CURES shall be contingent upon the availability
33 of adequate funds from the Department of Justice. The
34 Department of Justice may seek and use grant funds to pay the
35 costs incurred from the reporting of controlled substance
36 prescriptions to CURES. Funds shall not be appropriated from
37 the Contingent Fund of the Medical Board of California, the
38 Pharmacy Board Contingent Fund, the State Dentistry Fund, the
39 Board of Registered Nursing Fund, the Naturopathic Doctor's
40 Fund, or the Osteopathic Medical Board of California Contingent

1 Fund to pay the costs of reporting Schedule III controlled
2 substance prescriptions to CURES.

3 (c) CURES shall operate under existing provisions of law to
4 safeguard the privacy and confidentiality of patients. Data
5 obtained from CURES shall only be provided to appropriate
6 state, local, and federal persons or public agencies for
7 disciplinary, civil, or criminal purposes and to other agencies or
8 entities, as determined by the Department of Justice, for the
9 purpose of educating practitioners and others in lieu of
10 disciplinary, civil, or criminal actions. Data may be provided to
11 public or private entities, as approved by the Department of
12 Justice, for educational, peer review, statistical, or research
13 purposes, provided that patient information, including any
14 information that may identify the patient, is not compromised.
15 Further, data disclosed to any individual or agency as described
16 in this subdivision shall not be disclosed, sold, or transferred to
17 any third party.

18 (d) For each prescription for a Schedule II or Schedule III
19 controlled substance, the dispensing pharmacy shall provide the
20 following information to the Department of Justice in a
21 frequency and format specified by the Department of Justice:

22 (1) Full name, address, gender, and date of birth of the patient.

23 (2) The prescriber's category of licensure and license number;
24 federal controlled substance registration number; and the state
25 medical license number of any prescriber using the federal
26 controlled substance registration number of a
27 government-exempt facility.

28 (3) Pharmacy prescription number, license number, and
29 federal controlled substance registration number.

30 (4) NDC (National Drug Code) number of the controlled
31 substance dispensed.

32 (5) Quantity of the controlled substance dispensed.

33 (6) ICD-9 (diagnosis code), if available.

34 (7) Date of issue of the prescription.

35 (8) Date of dispensing of the prescription.

36 ~~SEC. 7.~~

37 *SEC. 10.* Section 11167 of the Health and Safety Code is
38 amended to read:

39 11167. Notwithstanding subdivision (a) of Section 11164, in
40 an emergency where failure to issue a prescription may result in

1 loss of life or intense suffering, an order for a controlled
2 substance may be dispensed on an oral order, an electronic data
3 transmission order, or a written order ~~not made on a controlled~~
4 ~~substance form as specified in Section 11162.1~~, subject to all of
5 the following requirements:

6 (a) The order contains all information required by subdivision
7 (a) of Section 11164.

8 (b) Any written order is signed and dated by the prescriber in
9 ink, and the pharmacy reduces any oral or electronic data
10 transmission order to hard copy form prior to dispensing the
11 controlled substance.

12 (c) The prescriber provides a written prescription ~~on a~~
13 ~~controlled substance prescription form that meets the~~
14 ~~requirements of Section 11162.1~~, by the seventh day following
15 the transmission of the initial order; a postmark by the seventh
16 day following transmission of the initial order shall constitute
17 compliance.

18 (d) If the prescriber fails to comply with subdivision (c), the
19 pharmacy shall so notify the Bureau of Narcotic Enforcement in
20 writing within 144 hours of the prescriber's failure to do so and
21 shall make and retain a hard copy, readily retrievable record of
22 the prescription, including the date and method of notification of
23 the Bureau of Narcotic Enforcement.

24 ~~SEC. 8.~~

25 *SEC. 11.* Section 11167.5 of the Health and Safety Code is
26 amended to read:

27 11167.5. (a) An order for a controlled substance classified in
28 Schedule II for a patient of a licensed skilled nursing facility, a
29 licensed intermediate care facility, a licensed home health
30 agency, or a licensed hospice may be dispensed upon an oral or
31 electronically transmitted prescription. If the prescription is
32 transmitted orally, the pharmacist shall, prior to filling the
33 prescription, reduce the prescription to writing in ink in the
34 handwriting of the pharmacist on a form developed by the
35 pharmacy for this purpose. If the prescription is transmitted
36 electronically, the pharmacist shall, prior to filling the
37 prescription, produce, sign, and date a hard copy prescription.
38 The prescriptions shall contain the date the prescription was
39 orally or electronically transmitted by the prescriber, the name of
40 the person for whom the prescription was authorized, the name

1 and address of the licensed skilled nursing facility, licensed
2 intermediate care facility, licensed home health agency, or
3 licensed hospice in which that person is a patient, the name and
4 quantity of the controlled substance prescribed, the directions for
5 use, and the name, address, category of professional licensure,
6 license number, and federal controlled substance registration
7 number of the prescriber. The original shall be properly endorsed
8 by the pharmacist with the pharmacy's state license number, the
9 name and address of the pharmacy, and the signature of the
10 person who received the controlled substances for the licensed
11 skilled nursing facility, licensed intermediate care facility,
12 licensed home health agency, or licensed hospice. A licensed
13 skilled nursing facility, a licensed intermediate care facility, a
14 licensed home health agency, or a licensed hospice shall forward
15 to the dispensing pharmacist a copy of any signed telephone
16 orders, chart orders, or related documentation substantiating each
17 oral or electronically transmitted prescription transaction under
18 this section.

19 *SEC. 12. No reimbursement is required by this act pursuant*
20 *to Section 6 of Article XIII B of the California Constitution*
21 *because the only costs that may be incurred by a local agency or*
22 *school district will be incurred because this act creates a new*
23 *crime or infraction, eliminates a crime or infraction, or changes*
24 *the penalty for a crime or infraction, within the meaning of*
25 *Section 17556 of the Government Code, or changes the definition*
26 *of a crime within the meaning of Section 6 of Article XIII B of the*
27 *California Constitution.*